

EXHIBIT 5

Daniel S. Elliott, M.D.

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

- - -

4 IN RE: C. R. BARD, INC., : MDL NO. 2187
5 PELVIC REPAIR SYSTEM :
6 PRODUCTS LIABILITY :
7 LITIGATION :

8 THIS DOCUMENT RELATES TO :

9 Becky Smith and Donald :Case No. 2:15-cv-16402
10 Mackie, :
11 Plaintiffs, :
12 v. :
13 C. R. BARD, INC. :
14 Defendant. :

- - -

15 JULY 29, 2019

- - -

16 Videotape deposition of
17 DANIEL S. ELLIOTT, MD, taken pursuant to
18 notice, was held at the law offices of
19 Reed Smith LLP, 136 Main Street, Suite
20 250, Princeton Forrestal Village,
21 Princeton, New Jersey 08540, beginning at
22 1:27 p.m., on the above date, before
23 Amanda Dee Maslynsky-Miller, a Certified
24 Realtime Reporter in and for the State of
 New Jersey.

- - -

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1 - - -
2 I N D E X
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4 Testimony of: DANIEL S. ELLIOTT, MD

5 By Mr. Buhr 7

6 - - -
7 E X H I B I T S
8 - - -

9
10 NO. DESCRIPTION PAGE
11 Elliott-1 Notice of Videotaped
12 Deposition of Dr. Daniel
S. Elliott 9
13 Elliott-2 Case-Specific Expert
14 Report 16
15 Elliott-3 List of Previous
Witness Testimony 27
16 Elliott-4 11/15/07 Dr. Julie
Crawford Medical Note 44
17 Elliott-5 11/20/17 Dr. Kim Medical
Record 50
18 Elliott-6 1/10/08 Dr. Julie
Crawford Medical Record 52
19 Elliott-7 1/11/08 Consent Form 67
20 Elliott-8 Hospital Record 76
21 Elliott-9 8/8/13 Hoth Note 93
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2 D E P O S I T I O N S U P P O R T I N D E X
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4
5 Direction to Witness Not to Answer
6 Page Line Page Line Page Line
7 None
8
9
10 Request for Production of Documents
11 Page Line Page Line Page Line
12 None
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14
15 Stipulations
16 Page Line Page Line Page Line
17 6 1
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20 Question Marked
21 Page Line Page Line Page Line
22 None
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24

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|--|---|
| <p style="text-align: right;">Page 6</p> <p>1 - - -</p> <p>2 (It is hereby stipulated and</p> <p>3 agreed by and among counsel that</p> <p>4 sealing, filing and certification</p> <p>5 are waived; and that all</p> <p>6 objections, except as to the form</p> <p>7 of the question, will be reserved</p> <p>8 until the time of trial.)</p> <p>9 - - -</p> <p>10 VIDEO TECHNICIAN: We are</p> <p>11 now on the record. My name is Dan</p> <p>12 Lawlor, I'm a videographer with</p> <p>13 Golkow Litigation Services.</p> <p>14 Today's date is July 29th, 2019,</p> <p>15 and the time is 1:27 p.m.</p> <p>16 This video deposition is</p> <p>17 being held in Princeton, New</p> <p>18 Jersey, in the Matter of Becky</p> <p>19 Smith versus C.R. Bard, Inc.,</p> <p>20 Pelvic Mesh. The deponent is</p> <p>21 Daniel Elliott. Counsel will be</p> <p>22 noted on the stenographic record.</p> <p>23 The court reporter is Amanda</p> <p>24 Miller and will now swear in the</p> | <p style="text-align: right;">Page 8</p> <p>1 to the best of your ability today?</p> <p>2 A. As long as they're stated</p> <p>3 clearly, no.</p> <p>4 Yes.</p> <p>5 Q. Fair enough.</p> <p>6 You've been deposed several</p> <p>7 times in the past; is that right?</p> <p>8 A. Correct.</p> <p>9 Q. You feel comfortable with</p> <p>10 the deposition process and the rules we</p> <p>11 typically like to follow?</p> <p>12 A. Yes.</p> <p>13 Q. So I won't go over the</p> <p>14 typical admonitions, then.</p> <p>15 But I will say that with the</p> <p>16 video conference here with the slight</p> <p>17 delay, make a special effort, and I'll do</p> <p>18 the same, to let each other finish and</p> <p>19 not talk over each other for the sake of</p> <p>20 the court reporter and just understanding</p> <p>21 each other.</p> <p>22 Is that fair?</p> <p>23 A. Yes, it is.</p> <p>24 Q. Let's start with just</p> |
| <p style="text-align: right;">Page 7</p> <p>1 witness.</p> <p>2 - - -</p> <p>3 DANIEL S. ELLIOTT, MD, after</p> <p>4 having been duly sworn, was</p> <p>5 examined and testified as follows:</p> <p>6 - - -</p> <p>7 VIDEO TECHNICIAN: Please</p> <p>8 proceed.</p> <p>9 - - -</p> <p>10 EXAMINATION</p> <p>11 - - -</p> <p>12 BY MR. BUHR:</p> <p>13 Q. Good afternoon, Doctor. My</p> <p>14 name is Eric Buhr, I represent the</p> <p>15 defendant in this case.</p> <p>16 Can you please state your</p> <p>17 full name for the record?</p> <p>18 A. Daniel Stephen Elliott.</p> <p>19 Q. And you understand you're</p> <p>20 here today as a retained expert for Becky</p> <p>21 Smith in her case against C.R. Bard?</p> <p>22 A. Correct.</p> <p>23 Q. Is there any reason you</p> <p>24 cannot understand and answer my questions</p> | <p style="text-align: right;">Page 9</p> <p>1 housekeeping and attach as Exhibit A a</p> <p>2 copy of the deposition notice.</p> <p>3 - - -</p> <p>4 (Whereupon, Exhibit</p> <p>5 Elliott-1, Notice of Videotaped</p> <p>6 Deposition of Dr. Daniel S.</p> <p>7 Elliott, was marked for</p> <p>8 identification.)</p> <p>9 - - -</p> <p>10 BY MR. BUHR:</p> <p>11 Q. Doctor, have you seen this</p> <p>12 deposition notice before today?</p> <p>13 A. Yes, I have.</p> <p>14 Q. It includes a long list of</p> <p>15 document requests. And I won't go</p> <p>16 through each one of them.</p> <p>17 I understand from our</p> <p>18 discussion off the record that you've</p> <p>19 already produced most or all of the</p> <p>20 records that would be responsive, except,</p> <p>21 perhaps, invoices regarding this case.</p> <p>22 Is that a correct</p> <p>23 understanding?</p> <p>24 A. That is what I understand as</p> |

Page 10

1 well.
 2 Q. So just to be clear, you
 3 haven't brought anything with you?
 4 A. No.
 5 You cut out on us a little
 6 bit. I think I understood your question,
 7 but there was a little bit of a gap
 8 there. You may just want to repeat it so
 9 I know.
 10 Q. Just to be clear, you didn't
 11 bring anything with you today to produce?
 12 A. That is correct, I did not
 13 bring anything.
 14 Q. You've been retained on
 15 behalf of Wagstaff Cartmell to provide
 16 expert testimony in this case; is that
 17 right?
 18 A. Correct.
 19 Q. And you previously provided
 20 expert reports and provided expert
 21 testimony in this MDL against C.R. Bard;
 22 is that right?
 23 A. Correct.
 24 Q. And, in fact, you previously

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1 provided a generic report on the involved
 2 products and were deposed on those
 3 generic opinions; is that right?
 4 A. Correct. Several years ago,
 5 yes.
 6 Q. So we'll try not to tread
 7 any old ground on those generic opinions.
 8 So today we're specifically
 9 discussing your opinions regarding Becky
 10 Smith. Is that consistent with your
 11 understanding?
 12 A. Yes, exactly.
 13 Q. Do you recall when you were
 14 first retained by the Wagstaff firm to
 15 provide expert opinion in Bard cases?
 16 A. I don't recall the exact
 17 time. I know I gave a general report and
 18 deposition four, five years ago. But I
 19 don't have the exact timeframe of that,
 20 though.
 21 Q. Do you know how many Bard
 22 cases you have provided expert opinion
 23 in?
 24 A. Off the top of my head,

Page 12

1 without a -- I would say three or four
 2 perhaps.
 3 Q. Do you know the total amount
 4 of time that you've spent in this
 5 litigation against Bard?
 6 MS. SCARCELLO: Object to
 7 the extent it calls for testimony
 8 about general opinions.
 9 THE WITNESS: No, I don't.
 10 I don't have that number.
 11 BY MR. BUHR:
 12 Q. Do you have any general
 13 estimate of the amount of hours you spent
 14 on the C.R. Bard cases?
 15 MS. SCARCELLO: Same
 16 objection.
 17 THE WITNESS: I don't keep
 18 any record.
 19 BY MR. BUHR:
 20 Q. You don't keep invoices that
 21 you submitted to the Wagstaff firm?
 22 A. No, I do not.
 23 Q. And am I correct that you
 24 charge \$700 per hour for case review and

Page 13

1 testimony?
 2 A. Correct.
 3 Q. Am I correct that you've
 4 also provided expert testimony in a
 5 number of pelvic mesh cases against
 6 Ethicon?
 7 A. Correct.
 8 Q. And are you retained through
 9 the Wagstaff firm for those cases as
 10 well?
 11 A. Yes.
 12 Q. Do you recall approximately
 13 how many Ethicon cases you've provided
 14 expert testimony in?
 15 A. I don't have an exact
 16 number. The majority of the work would
 17 be done with Ethicon as opposed to Bard,
 18 though.
 19 Q. Have you provided expert
 20 testimony in any other pelvic mesh
 21 litigation other than Ethicon and C.R.
 22 Bard?
 23 A. There was work done early on
 24 against -- with the Cook product, which

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| <p style="text-align: right;">Page 14</p> <p>1 is a non-mesh. And then a little bit of 2 work with the AMS products. I don't know 3 how far those extended, but I didn't do 4 any patient case-specific reviews, and I 5 do not believe I turned in any general 6 expert report. But I looked at issues 7 originally. 8 Q. Do you have any estimate for 9 how much time you spent specifically on 10 the Becky Smith case? 11 A. I don't have an exact 12 number. That work was done in May of 13 this year and sent to the Wagstaff firm. 14 So they have that, which I've been told 15 will be provided to you. 16 Generally, they take several 17 hours or more. But I don't have a 18 specific recollection of this one. 19 Q. So when you say "they have 20 that," are you referring to an invoice 21 for your time? 22 A. That is correct. 23 MR. BUHR: And then, 24 counsel, I know we mentioned this</p> | <p style="text-align: right;">Page 16</p> <p>1 MS. SCARCELLO: Object to 2 the form of the question. 3 THE WITNESS: I would 4 just -- I would have to be 5 guessing, because I have not seen 6 that May invoice. I would suspect 7 the May invoice would be around 8 the four- to seven-hour range. 9 Again, that's very much of a 10 guess. 11 And then in July, it's 12 around the same amount of time. 13 BY MR. BUHR: 14 Q. I assume you haven't 15 submitted your -- an invoice for your 16 July time; is that right? 17 A. That's correct. That will 18 be done at the end of the month. So in a 19 few days. 20 MR. BUHR: Let's go ahead 21 and attach your case-specific 22 expert report as Exhibit-2, I 23 believe it would be. 24 - - -</p> |
| <p style="text-align: right;">Page 15</p> <p>1 prior to the deposition, but for 2 the record, you'll agree to 3 produce those to our offices, 4 whatever invoices you have 5 specific to this Becky Smith case? 6 MS. SCARCELLO: Yes. 7 BY MR. BUHR: 8 Q. Have you spent additional 9 time since the submission of those 10 invoices, or invoice, around the May 11 timeframe? 12 Do you have an estimate for 13 how much additional time, if any, you've 14 spent on this case? 15 A. It's been several hours 16 spent this month alone. So since May, 17 there's been none until this month, July. 18 And, again, that would be several hours 19 reviewing depositions and expert reports. 20 Q. So, then, would it be 21 approximately six hours you spent in 22 total on this case, if I'm understanding 23 what you said, in your time spent in May 24 and your time spent in July?</p> | <p style="text-align: right;">Page 17</p> <p>1 (Whereupon, Exhibit 2 Elliott-2, Case-Specific Expert 3 Report, was marked for 4 identification.) 5 - - - 6 BY MR. BUHR: 7 Q. So what we've attached as 8 Exhibit-2, does that appear to be your 9 complete expert report in this case? 10 A. It appears to be signed and 11 dated May 24th, 2019. It includes my 12 report, my -- and my C.V. and my reliance 13 list. 14 Q. And does this report contain 15 all of the opinions that you intend to 16 offer in this case specific to Becky 17 Smith? 18 A. Up to this point, yes. If 19 new material becomes available, 20 obviously, that would change. But as of 21 today, July 29th, this is complete. 22 Q. And can you generally 23 describe for me how you go about forming 24 your opinions?</p> |

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| <p style="text-align: right;">Page 18</p> <p>1 A. Forming my opinions on this 2 case or anything I do in my normal daily 3 work would be the same. It would be 4 reviewing the outside medical records, 5 talking with the patient usually, though 6 in this case I can't talk to her, 7 obviously, and based upon my experience, 8 my review of the medical literature, 9 discussions with colleagues, et cetera, 10 come up with an opinion ruling in or 11 ruling out various different pathologies. 12 Q. And so Exhibit B to your 13 expert report is your reliance list. 14 And that's everything you 15 relied on in forming your opinions at the 16 time of your expert report, correct? 17 A. Correct. 18 Q. And how did you go about 19 compiling these materials? 20 A. As part of my usual, I ask 21 whatever law firm it happens to be, this 22 time, obviously, it's Wagstaff and 23 Cartmell, give me all medical records 24 that are available, all depositions, all</p> | <p style="text-align: right;">Page 20</p> <p>1 A. Well, I request all medical 2 records that are available. And so I'm 3 at the mercy of the law firm of giving me 4 whatever they can get ahold of. 5 If I find an operative note 6 or something that I don't have, I ask 7 them for it. But that wasn't in this 8 particular case. So as far as I know, 9 I've been given all of the records. 10 Q. And you kind of alluded to 11 this a little bit already, but just to be 12 clear, at the time you formed your 13 opinions and signed your report, you 14 didn't have the depositions of any of the 15 treating physicians in this case; is that 16 right? 17 A. That is correct. 18 Q. And did you feel that you 19 could form your opinions without the 20 testimony of the implanting and 21 explanting physicians? 22 A. I can essentially form my 23 opinions based upon the medical records, 24 and then augment that with the</p> |
| <p style="text-align: right;">Page 19</p> <p>1 expert reports, everything. And then I 2 review whatever they give me. 3 Q. Did you feel you had 4 adequate materials to form your opinion 5 at that time? 6 A. Yeah, at that time. Yes. 7 There's been added on since that time, 8 with depositions of the implanting doctor 9 and one of the revision surgeons, and 10 then the -- what would you call it? The 11 defense expert witness. I've reviewed 12 that since then. 13 Q. What do you mean by -- 14 A. But my opinions did not -- 15 Sorry, go ahead. 16 Q. I didn't want to cut you off 17 if you were still finishing your answer. 18 A. I was going to finish by 19 saying the reviewing of those further 20 documents, the deposition and expert 21 report did not change my opinions 22 significantly, it mainly supported them. 23 Q. Did you request any 24 additional medical records?</p> | <p style="text-align: right;">Page 21</p> <p>1 deposition. 2 Had the depositions shown a 3 significant opinion difference or changed 4 my opinion one way or the other 5 significantly, then I would have asked 6 for a supplemental report to be filed. 7 Q. So several times, I believe, 8 you used the term "significantly." 9 Did reviewing those 10 depositions after your expert report 11 change your opinions in any way? 12 A. No, they just reinforced 13 them. So it didn't change. Reinforced. 14 Q. Did you review the entirety 15 of those depositions or just excerpts? 16 A. No, as per my usual, I asked 17 for the entire deposition, all 18 however-many-hundreds of pages they are, 19 and then I go through them. So I do not 20 get ever a summary. 21 Q. Do you get a summary, any 22 type of summary, of the medical records, 23 or do you review those in their entirety 24 as well?</p> |

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1 A. I review them in their
2 entirety. I found that chronologies as
3 provided, they weren't provided in this
4 case, but if they are provided, they
5 tended to not be very accurate. So I did
6 it all myself, every single page.
7 Q. So, then, just to be clear,
8 even though you reviewed additional
9 materials since you signed your expert
10 report, you still feel it's complete and
11 accurate?
12 A. Yes.
13 Q. And it contains all of the
14 opinions you intend to offer and your
15 basis for those opinions?
16 A. As I stated before, unless
17 new information were to be provided
18 that's not available as of July 29th,
19 2019. But right now it is complete.
20 Q. I believe you mentioned
21 reviewing an expert report from the
22 defense.
23 What specifically are you
24 referring to?

Page 23

1 A. There was a Dr. -- I won't
2 pronounce his name correctly, so I have
3 to apologize -- Guidice, Guidice,
4 something like that.
5 Q. I say Guidice, but I don't
6 know if that's correct either, to be
7 honest.
8 So you reviewed his report?
9 A. Correct.
10 Q. Did you have any significant
11 disagreements with his report?
12 A. Yeah, that's a -- we'd have
13 to go through point by point of his
14 report. But, yes, I have some major
15 disagreements.
16 Q. Did you do anything to
17 specifically prepare for the deposition
18 today?
19 A. Other than just on my own,
20 reviewing my expert report, as I said --
21 mentioned earlier, reviewing the
22 depositions from the two physicians and
23 then the expert report, Dr. Guidice, and
24 I had a 15-minute meeting with counsel

Page 24

1 this afternoon.
2 Q. You had a 15-minute meeting
3 with counsel today?
4 A. Correct.
5 Q. And was that with the
6 counsel that's here at the deposition
7 today?
8 A. Correct.
9 Q. There was also a subsequent
10 deposition of plaintiff Becky Smith that
11 took place maybe a month and-a-half ago.
12 Did you review that
13 deposition transcript?
14 A. I have not seen that one.
15 Q. So the only deposition of
16 the plaintiff that you've reviewed is the
17 deposition that took place in 2017; is
18 that right?
19 A. Correct.
20 Q. Is that something you would
21 like to review, her new deposition?
22 A. Yes.
23 Q. And you have not personally
24 examined Becky Smith; is that right?

Page 25

1 A. Correct.
2 Q. I believe in some prior Bard
3 cases you performed examinations, what we
4 sometimes refer to as an IME.
5 Do you recall that?
6 A. Yes.
7 Q. And why did you not do an
8 IME or any type of examination with Becky
9 Smith?
10 A. I was under the
11 understanding that there was an agreement
12 that if this case, or whatever you call
13 it, were to proceed forward, then I would
14 do one prior to any trial case.
15 Q. So is that something you
16 think would be helpful in forming your
17 opinions?
18 A. Yes.
19 Q. Have you spoken with Becky
20 Smith?
21 A. No.
22 Q. Have you spoken with any of
23 her doctors?
24 A. No.

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| <p style="text-align: right;">Page 26</p> <p>1 Q. Can you describe generally 2 for me your method in drafting this 3 expert report?</p> <p>4 A. It would be the same as all 5 reports I do. I review all of the 6 medical records, write down a chronology 7 with key comments made within the 8 records. From there, formulate a 9 differential diagnosis ruling in or 10 ruling out various different pathologies. 11 And then I write the report 12 up and then come to conclusions, based 13 upon the information I had at that point 14 in time.</p> <p>15 Q. So would you personally take 16 notes as you're reviewing the medical 17 records?</p> <p>18 A. No. I do it -- as I go, I 19 write it. So there's no separate set of 20 notes.</p> <p>21 Q. And does the report contain 22 everything you ruled in and ruled out in 23 your differential diagnosis?</p> <p>24 A. Correct. As what is</p> | <p style="text-align: right;">Page 28</p> <p>1 Witness Testimony, was marked for 2 identification.)</p> <p>3 - - -</p> <p>4 BY MR. BUHR:</p> <p>5 Q. So is this an accurate list 6 of your previous testimony?</p> <p>7 A. Well, I don't keep a list of 8 my testimony, so this would have come 9 from the Cartmell firm. So I cannot 10 attest to the accuracy or completeness of 11 it.</p> <p>12 It looks fairly complete. 13 But, again, I don't -- in retrospect, 14 can't say if it's complete.</p> <p>15 Q. Can you tell by looking at 16 it what time period this covers?</p> <p>17 A. It would cover roughly 2011 18 to the present.</p> <p>19 Q. Does it appear to be roughly 20 in chronological order, to the best you 21 can tell?</p> <p>22 A. Well, the very first one 23 says Coloplast versus Generical Medical 24 Devices and the very last one is the same</p> |
| <p style="text-align: right;">Page 27</p> <p>1 indicated on Page 4 of my report going to 2 Page 5, that would be my standard 3 differential diagnosis.</p> <p>4 Q. Did you have any assistance 5 preparing your report?</p> <p>6 A. None.</p> <p>7 Other than the reliance 8 list. Sorry, I should -- I did not type 9 up the reliance list. I typed up the 10 medical billing records, the depositions 11 and then the Wagstaff firm provided the 12 other. So I did not personally type that 13 up.</p> <p>14 Q. I'd like to attach, just for 15 the record, your list of previous 16 testimony that was provided to us. This 17 wasn't attached to your expert report, it 18 was provided to us separately.</p> <p>19 MR. BUHR: So I just want to 20 make sure it was attached for the 21 record. Let's do it as Exhibit-3.</p> <p>22 - - -</p> <p>23 (Whereupon, Exhibit 24 Elliott-3, List of Previous</p> | <p style="text-align: right;">Page 29</p> <p>1 thing. So, I don't know, it says, In 2 regards to Mentor ObTape, that was -- 3 wait, I'm sorry, that's different.</p> <p>4 I would have to say, yes, it 5 does look accurate. I just don't know 6 why that Mentor -- the last one is Mentor 7 ObTape. I don't know how that fits in 8 there. But it looks fairly accurate.</p> <p>9 Q. Do you recall roughly when 10 you last testified?</p> <p>11 A. Well, "testified," do you 12 mean -- does that mean a deposition?</p> <p>13 Q. Yes.</p> <p>14 A. Or a trial, in the 15 courtroom?</p> <p>16 Q. Either one.</p> <p>17 A. Last deposition I gave was 18 last weekend. Last time I was in a 19 courtroom was February of 2018.</p> <p>20 Q. Is your deposition last 21 weekend listed on this report?</p> <p>22 A. No.</p> <p>23 Q. So what case was that in?</p> <p>24 A. That was a deposition --</p> |

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|--|--|
| <p style="text-align: right;">Page 30</p> <p>1 case-specific depositions on three Bard 2 cases -- excuse me, three Ethicon cases 3 and one Bard case. 4 Q. What was the product at 5 issue in the Bard case? 6 A. Avaulta. And the individual 7 also had an AMS sling, but that was not 8 part of the deposition. 9 Q. And what were the Ethicon 10 products involved in those cases? 11 A. Two Prolift?s and one TVT-O. 12 Q. Is the Prolift? a product to 13 treat pelvic organ prolapse? 14 A. Correct. 15 Q. And the TVT-O is a pelvic 16 mesh product to treat stress urinary 17 incontinence? 18 A. Correct. 19 Q. And you provided expert 20 opinion that those products were 21 defective and caused injury; would that 22 be right? 23 A. Correct. 24 Q. And with respect to your</p> | <p style="text-align: right;">Page 32</p> <p>1 caused injury; is that right? 2 A. Correct. 3 Q. So turning more specifically 4 to Becky Smith, you referenced your 5 general differential diagnosis list on 6 Pages 4 and 5 of your report, correct? 7 A. Yes. 8 Q. And you were able to rule 9 all of those out as potentiality 10 alternative causes? 11 A. Well, no, I don't rule them 12 all out, because some of those include 13 mesh complications. So some of them are 14 ruled in, some of them are ruled out. 15 The majority are ruled out. 16 Q. So you ruled out everything 17 other than those related to mesh? 18 A. Well, we would have to go -- 19 sure, I don't want to make a blanket 20 statement and miss something here, but 21 either mesh or mesh-specific 22 complications, yes, I ruled them out. 23 Q. So just to be clear as a 24 starting point, that I understand the</p> |
| <p style="text-align: right;">Page 31</p> <p>1 courtroom testimony in February 2018, do 2 you recall what case that was and what it 3 involved? 4 A. It was a Prolift? case with 5 Wagstaff Cartmell in Indiana, if that 6 helps. 7 Q. Are there additional Ethicon 8 products that you provided expert opinion 9 on? 10 A. TVT as well, and TVT-Secur. 11 Q. And your opinion is all 12 those products were defective and caused 13 injury? 14 A. Correct. 15 MS. GRIFFIN: Eric, just for 16 the record, that came in a little 17 spotty, in case you want to repeat 18 that. 19 MR. BUHR: Thank you for 20 that. 21 BY MR. BUHR: 22 Q. So you provided expert 23 opinion that all the products you just 24 listed from Ethicon were defective and</p> | <p style="text-align: right;">Page 33</p> <p>1 opinions that you intend to offer here, 2 with respect to Becky Smith's specific 3 injuries, am I correct that you're 4 offering an opinion that the Bard mesh 5 implants caused plaintiff, Becky Smith, 6 pelvic pain and dyspareunia and mesh 7 extrusion? 8 A. As summarized on Page 18 of 9 my report, starting on Page 18, yes, 10 pelvic pain, vaginal pain and dyspareunia 11 resulting from the complications caused 12 by the presence of the mesh in her body. 13 Q. So just to be clear, you're 14 not offering an opinion that she has any 15 other injuries such as voiding 16 dysfunction or anything like that, right? 17 A. Well, voiding dysfunction 18 can be caused by the presence of the 19 mesh, the removal of the mesh, or 20 dysfunction caused by. So we would have 21 to be very specific. 22 From what I understand, as 23 of now she was not complaining of 24 significant voiding dysfunction. But if</p> |

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1 you had something, I'd have to see it in
2 the records. I didn't see that.

3 Q. Well, I didn't see anything
4 either. I just want to make sure that
5 what you're alleging her injuries are
6 related to the mesh is encompassed by
7 pelvic pain, dyspareunia and extrusion
8 requiring removal of the mesh, correct?

9 A. Correct. As of right now,
10 yes.

11 Q. You're aware that plaintiff
12 has complained of fecal incontinence; is
13 that right?

14 A. Yes.

15 Q. And you're not offering an
16 opinion that that was caused by the mesh;
17 is that right?

18 A. As of what I know right now,
19 it is very difficult to draw a logical
20 physiologic relationship between the
21 presence or absence of the mesh or
22 surgery for the mesh causing fecal
23 incontinence.

24 Q. So you are not offering an

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1 opinion that her fecal incontinence was
2 caused by the mesh?

3 A. Well, as I stated, as of
4 what I know right now, I cannot draw a
5 logical connection between the mesh and
6 the surgery to remove the mesh with fecal
7 incontinence.

8 Q. And you would agree that
9 plaintiff's treating physician, Dr.
10 Denman, also concluded that the -- her
11 fecal incontinence was not related to the
12 mesh; is that right?

13 A. Yes.

14 Q. Is it your opinion that both
15 the Avaulta and the Align are responsible
16 for her injuries?

17 A. They are both contributing.

18 Q. Can you say what percentage
19 of her injuries are related to the
20 Avaulta versus the Align?

21 A. It's very difficult to
22 assign a percentage. However, due to the
23 significantly enlarged volume of the
24 Avaulta mesh, the multiple arms and the

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1 collagen coating, it is going to be more
2 responsible than the TVT-O -- excuse me,
3 the Align.

4 Q. But you intend to offer an
5 opinion that the Align is responsible for
6 her pelvic pain and dyspareunia?

7 A. It will be a contributing
8 factor. Since the mesh is identical and
9 it's going in the same obturator foramen,
10 it is not going to be helping any.

11 What I'm saying is, I cannot
12 assign a percentage. More likely, the
13 Avaulta is going to be the much greater
14 percentage, just, as I mentioned, due to
15 the volume and the presence of the
16 collagen coating.

17 Q. And you're saying that the
18 mesh of the Align and the Avaulta are
19 identical?

20 MS. SCARCELLO: Object to
21 the form.

22 THE WITNESS: No, they are
23 not identical. The meshes are
24 quite similar. But the Align does

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1 not have a collagen coating like
2 the Avaulta Plus, which Ms. Smith
3 has, or had.

4 BY MR. BUHR:

5 Q. Are you offering an opinion
6 that the extrusion was related to the
7 Align product as opposed to the Avaulta?

8 A. From what I understand at
9 this point, the Avaulta product was the
10 product that had extruded, not the Align.

11 Q. I understand, from your
12 prior testimony -- well, let me confirm
13 if my understanding is correct.

14 Have you ever implanted a
15 transvaginal mesh for pelvic organ
16 prolapse?

17 A. No. I have chosen not to do
18 that.

19 Q. Have you implanted
20 midurethral slings made out of
21 polypropylene?

22 A. Yes.

23 Q. Have you ever implanted the
24 Align?

| | |
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| <p style="text-align: right;">Page 38</p> <p>1 A. No.</p> <p>2 Q. What midurethral slings have</p> <p>3 you implanted?</p> <p>4 A. I've gone through a series</p> <p>5 of them and had problems, and that's why</p> <p>6 there's been a series.</p> <p>7 I started with the Mentor</p> <p>8 ObTape in the early 2000s, probably 2002</p> <p>9 or '03, around that time. We obviously</p> <p>10 had major problems with that. Then I</p> <p>11 switched to the AMS product called the</p> <p>12 Monarc, used that for a couple of years.</p> <p>13 But we had a significant amount of</p> <p>14 problems of pain for the patient for</p> <p>15 that, so I stopped that. And then used</p> <p>16 the Coloplast product, their</p> <p>17 transobturator sling.</p> <p>18 Q. And is that made of</p> <p>19 polypropylene?</p> <p>20 A. Correct.</p> <p>21 Q. And it's implanted</p> <p>22 transobturally -- through the</p> <p>23 transobturator, sorry, similar to the</p> <p>24 Align sling; is that right?</p> | <p style="text-align: right;">Page 40</p> <p>1 are within the standard of care?</p> <p>2 A. In the properly consented</p> <p>3 patient and with a surgeon who knows what</p> <p>4 they're doing and can handle the</p> <p>5 complications, it is within the standard</p> <p>6 of care.</p> <p>7 Q. Are they generally</p> <p>8 considered safe and effective in the</p> <p>9 medical community?</p> <p>10 A. The general community? I</p> <p>11 can't speak for everybody. But there</p> <p>12 have been position statements making</p> <p>13 that, that's what they state.</p> <p>14 Q. Are you referring to the</p> <p>15 AUGS position statement?</p> <p>16 A. That's one of them.</p> <p>17 Q. Are you a member of AUGS?</p> <p>18 A. Yes.</p> <p>19 Q. Do you agree with that</p> <p>20 position statement?</p> <p>21 A. I agree that it has been</p> <p>22 the -- that statement is long, with</p> <p>23 multiple points to it. So I can't give a</p> <p>24 blanket yes or no to it. We'd have to go</p> |
| <p style="text-align: right;">Page 39</p> <p>1 A. Correct. It's a</p> <p>2 transobturator sling, correct.</p> <p>3 Q. And would you agree that all</p> <p>4 of those products have a risk of pelvic</p> <p>5 pain and dyspareunia?</p> <p>6 A. All the mesh slings, to a</p> <p>7 varying degree, have a problem with</p> <p>8 dyspareunia, scarring, mesh contraction,</p> <p>9 foreign body reaction; so yes.</p> <p>10 Q. And that includes the</p> <p>11 Coloplast sling?</p> <p>12 A. Correct.</p> <p>13 Q. And you still implant that</p> <p>14 today?</p> <p>15 A. Very rarely. I used to, and</p> <p>16 then as of 2011 or so, the numbers</p> <p>17 plummeted to one or two a year from a</p> <p>18 high of about 100 to 150. And now</p> <p>19 there's maybe a few a year I do. I can't</p> <p>20 give you an exact number, roughly 5 out</p> <p>21 of 100 a year for unique patient</p> <p>22 situations.</p> <p>23 Q. Do you agree that the</p> <p>24 midurethral slings made of polypropylene</p> | <p style="text-align: right;">Page 41</p> <p>1 through each point.</p> <p>2 But I agree it has been</p> <p>3 studied, and I agree that there have been</p> <p>4 advances with that product. But there</p> <p>5 have also been significant complications</p> <p>6 associated with it. And that's where the</p> <p>7 problem occurs with me.</p> <p>8 Q. So at the time of Ms.</p> <p>9 Smith's implant in 2008, you agree it was</p> <p>10 within the standard of care for Dr. Kim</p> <p>11 to implant the Align midurethral sling to</p> <p>12 treat her stress urinary incontinence; is</p> <p>13 that right?</p> <p>14 A. Correct. I have no fault</p> <p>15 with Dr. Kim for implanting that at that</p> <p>16 point in time.</p> <p>17 Q. Right. And one of the</p> <p>18 opinions listed in your report is that</p> <p>19 the treating doctor, including Dr. Kim,</p> <p>20 acted within the standard of care.</p> <p>21 Is that an opinion that you</p> <p>22 intend to offer?</p> <p>23 A. Yes, I agree with that, in</p> <p>24 2008 when it was put in.</p> |

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| <p style="text-align: right;">Page 42</p> <p>1 Q. Do you also agree that it</p> <p>2 was within the standard of care in 2008</p> <p>3 to implant mesh for treatment of pelvic</p> <p>4 organ prolapse?</p> <p>5 A. Correct. As of January of</p> <p>6 2008, I agree that was within the</p> <p>7 standard of care.</p> <p>8 Q. So you agree it was within</p> <p>9 the standard of care to implant the</p> <p>10 Avaulta Plus in 2008?</p> <p>11 A. Well, in 2008, we were in</p> <p>12 our very infancy of knowing what was</p> <p>13 going on with meshes. I had chosen not</p> <p>14 to implant meshes, I didn't see a benefit</p> <p>15 for them, but I didn't feel they would be</p> <p>16 wrong. We were seeing increases in</p> <p>17 complications slowly rolling in.</p> <p>18 But as of January 2008, when</p> <p>19 that was implanted, I would find no fault</p> <p>20 in that, it was within the standard of</p> <p>21 care. So I agree with what I've stated</p> <p>22 in my report.</p> <p>23 Q. Would it be within the</p> <p>24 standard of care to implant mesh to treat</p> | <p style="text-align: right;">Page 44</p> <p>1 pelvic mesh and reconstructive surgery</p> <p>2 exam, if you have a grade 2 and above,</p> <p>3 it's acceptable to treat. But it has to</p> <p>4 be a discussion with the patient.</p> <p>5 Q. The doctor that performed a</p> <p>6 hysterectomy at the same time the mesh</p> <p>7 was implanted was Dr. Crawford; is that</p> <p>8 right?</p> <p>9 A. Correct.</p> <p>10 Q. Were you aware that Dr.</p> <p>11 Crawford found that Becky Smith did not</p> <p>12 have any significant cystocele?</p> <p>13 A. That's what I've heard, yes.</p> <p>14 MR. BUHR: And let's just go</p> <p>15 ahead and attach that record as</p> <p>16 Exhibit-4, just to make sure we're</p> <p>17 looking at the specifics.</p> <p>18 - - -</p> <p>19 (Whereupon, Exhibit</p> <p>20 Elliott-4, 11/15/07 Dr. Julie</p> <p>21 Crawford Medical Note, was marked</p> <p>22 for identification.)</p> <p>23 - - -</p> <p>24 BY MR. BUHR:</p> |
| <p style="text-align: right;">Page 43</p> <p>1 pelvic organ prolapse -- well, strike</p> <p>2 that.</p> <p>3 Would it be within the</p> <p>4 standard of care in 2008 to implant the</p> <p>5 Avaulta Plus if the patient did not have</p> <p>6 pelvic organ prolapse?</p> <p>7 A. Well, it is -- the Avaulta</p> <p>8 or the Avaulta Plus, Avaulta Solo, is</p> <p>9 defined for prolapse. If a woman has</p> <p>10 absolutely no prolapse, you would not</p> <p>11 want to implant it, because it's designed</p> <p>12 to treat prolapse.</p> <p>13 Q. What if the patient had a</p> <p>14 mild prolapse but was asymptomatic, would</p> <p>15 it be within the standard of care to</p> <p>16 implant the Avaulta mesh?</p> <p>17 A. That becomes a judgment</p> <p>18 call. That one has to be a discussion</p> <p>19 with the patient. If you are going in to</p> <p>20 operate already for another indication,</p> <p>21 and they have a low-grade prolapse, it</p> <p>22 depends what grade you're talking, we</p> <p>23 have to use specifics.</p> <p>24 Technically, for the female</p> | <p style="text-align: right;">Page 45</p> <p>1 Q. Do you have that record in</p> <p>2 front of you, Doctor?</p> <p>3 A. Yes, I do. I have, as you</p> <p>4 said, Exhibit-4. And this is dated</p> <p>5 November 15th, 2007. It's a note by Dr.</p> <p>6 Kim -- no, I'm sorry, Dr. Crawford, Julie</p> <p>7 Crawford.</p> <p>8 Q. And if you turn to -- well,</p> <p>9 before we get there. On Page Bates</p> <p>10 number 8, they list the past surgical</p> <p>11 history.</p> <p>12 Number 2 is, Prior bilateral</p> <p>13 tubal ligation.</p> <p>14 Can you explain what that</p> <p>15 is?</p> <p>16 A. That's for -- most likely,</p> <p>17 for sterility. So they ligate the tubes,</p> <p>18 analogous to a vasectomy in a male. It</p> <p>19 was done laparoscopically.</p> <p>20 Q. Is that a procedure that can</p> <p>21 lead to any type of pelvic pain or</p> <p>22 dyspareunia?</p> <p>23 A. It would be exceedingly</p> <p>24 rare. That's a small procedure done</p> |

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| <p style="text-align: right;">Page 46</p> <p>1 laparoscopically with small cameras. So 2 I'm sure we can find a case report here 3 or there, but this would be an 4 exceedingly small risk. 5 Q. Is it possible to develop 6 adhesions following that type of 7 procedure? 8 A. Adhesions could happen up in 9 the abdomen. 10 Q. And adhesions are 11 essentially scar tissue, right? 12 A. They are a type of scar 13 tissue. 14 Q. And they can lead to pain? 15 A. There have been reports of 16 that, yes. 17 Q. Is this something you 18 considered in your differential diagnosis 19 of Becky Smith's pelvic pain and 20 dyspareunia? 21 A. Correct. And prior to her 22 surgery, her implant surgery on January 23 15th, 2008, I did not see any record of 24 pelvic pain.</p> | <p style="text-align: right;">Page 48</p> <p>1 the fibroids. 2 Q. Are you familiar with the 3 potential complications from that type of 4 procedure? 5 A. I do not do that procedure, 6 but I am familiar with the types of pain 7 that they could have. Same thing with 8 fibroids. 9 And, again, as I mentioned 10 before, I didn't see anything documented 11 in the records attributing any of her 12 conditions, prior to her 2008 surgery, to 13 procedures such as that. 14 Q. Under medications, she's 15 taking Lexapro. 16 And I think you note in your 17 record that she had preexisting 18 depression prior to the implant meshes, 19 right? 20 A. Correct. 21 Q. Going on to the next page, 22 Dr. Crawford performed an exam, right? 23 A. Correct. Starting on the 24 Bates number 8 going to, it looks like,</p> |
| <p style="text-align: right;">Page 47</p> <p>1 Q. So you ruled it out because 2 she didn't complain of any pelvic pain at 3 that time? 4 A. Correct. Following the 5 surgery, adhesions, et cetera, you're 6 going to have -- it's not a delayed 7 development like we see in the meshes; 8 it's immediate. And there's no record of 9 anybody attributing any abdominal pain, 10 pelvic pain, attributing it to any 11 adhesions. 12 If you have those records, 13 I'd like to see it. I did not see 14 anything in the records. 15 Q. They also list a 2003 16 endometrial ablation. 17 Can you describe for the 18 jury what that is? 19 A. Well, that falls definitely 20 into the benign GYN land, which I do not 21 do these procedures. Usually, this is 22 done for uterine fibroids; usually. And 23 it's to help reduce the severity or 24 bleeding, abnormal bleeding, caused by</p> | <p style="text-align: right;">Page 49</p> <p>1 just 9. 2 Q. And the vaginal exam notes, 3 No evidence of a significant cystocele or 4 rectocele, appears well supported. 5 Is that right? 6 A. That is what she states as 7 of November 15th, 2007. 8 Q. And that was just a month 9 prior to her implant surgery, right? 10 A. Well, technically, like two 11 and-a-half months. But it was close. 12 Because her surgery was -- actually, it 13 was, like, two months. 14 Not to be difficult, just 15 for specifics here. January 15, '08 was 16 her surgery. 17 Q. You're right. 18 So about two months prior to 19 her surgery, Dr. Crawford did not find 20 any evidence of a significant cystocele 21 or rectocele? 22 A. Correct. On her exam on 23 that day, that's what she reported. 24 Q. And then she sees Dr. Kim a</p> |

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| <p style="text-align: right;">Page 50</p> <p>1 few weeks later, on November 30th. 2 MR. BUHR: And let's go 3 ahead and attach Dr. Kim's records 4 as Exhibit-5. 5 - - - 6 (Whereupon, Exhibit 7 Elliott-5, 11/20/17 Dr. Kim 8 Medical Record, was marked for 9 identification.) 10 - - - 11 BY MR. BUHR: 12 Q. Do you have those records in 13 front of you now, Doctor? 14 A. Yes, I do. 15 Q. So on Page -- if you go to 16 Page 12 and 13 of the Bates numbers, this 17 is the visit with Dr. Kim on November 18 30th, 2007. 19 A. Correct. 20 Q. And under assessment -- 21 actually, under examination, it says she 22 does have a grade 1 to 2 cystocele and a 23 mild rectocele. 24 Do you see that?</p> | <p style="text-align: right;">Page 52</p> <p>1 Q. And Dr. Kim did not repair 2 the mild rectocele, right? 3 A. Correct. 4 Q. So would you agree that the 5 grade 1 to 2 cystocele is a mild 6 cystocele? 7 A. Grade 1 is mild. Grade 2 is 8 not. It's in the realm of more 9 significant. And prolapses vary from 10 day-to-day depending how the woman is, 11 the time of day, how much standing they 12 have been doing. So it's not uncommon to 13 have a variable exam. 14 Q. Going back to Dr. Crawford's 15 records -- 16 MR. BUHR: Actually, do we 17 have her January 10th, 2008 18 record? 19 MS. GRIFFIN: We do. And 20 that can be marked as Exhibit 21 Number 6. 22 - - - 23 (Whereupon, Exhibit 24 Elliott-6, 1/10/08 Dr. Julie</p> |
| <p style="text-align: right;">Page 51</p> <p>1 A. Yes, I do. 2 Q. And what symptoms can 3 cystocele and rectocele cause? 4 A. Fullness, pressure, 5 sensation of something falling out; 6 asymptomatic, retention of urine, 7 retention of stool. 8 Again, I think I mentioned 9 pelvic pressure. Symptoms such as that, 10 or those. 11 Q. Prolapse can cause pelvic 12 pain and dyspareunia, too, right? 13 A. Well, pelvic pain, not 14 necessarily. Pelvic pain would be 15 different. 16 Pelvic pressure can -- it 17 can interfere with sexual activity, 18 depending upon the severity of the 19 prolapse. They should be very specific. 20 Pelvic pain is not something 21 we normally attribute, unless it's a 22 major, major prolapse where the vagina 23 has everted itself and it's irritating on 24 the clothing and things.</p> | <p style="text-align: right;">Page 53</p> <p>1 Crawford Medical Record, was 2 marked for identification.) 3 - - - 4 BY MR. BUHR: 5 Q. Do you have that record, 6 Doctor? 7 A. Yes, I do. 8 Q. On Bates number ending in 9 27, under the physical examination, about 10 three or four sentences above the end of 11 that paragraph, it says, On my exam, 12 there is no evidence of significant 13 cystocele or rectocele and she appears 14 apically supported. However, on exam by 15 Dr. Kim, she has a mild rectocele and 16 cystocele. 17 Do you see that language? 18 A. Yes, I do. 19 Q. So do you have any criticism 20 of implanting the Avaulta product in a 21 patient with only mild cystocele and is 22 asymptomatic? 23 A. I have criticism of 24 implanting the Avaulta product. However,</p> |

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1 on Dr. Kim's examination, grade 1 is low,
2 grade 2 is acceptable. And so that
3 becomes a judgment call by the doctor who
4 is there. And, as I mentioned, prolapses
5 vary from day-to-day.

6 If I were operating with a
7 doctor who I felt was doing something
8 wrong, I wouldn't operate with him. I
9 wouldn't do a combined case. Dr.
10 Crawford just mentions it, so I don't
11 have a criticism, really. If it were
12 only a grade 1, that would be different.
13 But it reports grade 2.

14 Q. And you agree she was
15 asymptomatic at this time with respect to
16 her cystocele?

17 A. I didn't see anything in the
18 records indicating significant prolapse
19 symptoms.

20 But they were going to be
21 doing an anti-incontinence procedure, so
22 it's quite common to do a combined repair
23 when you're doing that, because otherwise
24 it will affect your incontinence

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1 procedure.

2 Q. So you stand by your opinion
3 that Dr. Kim acted within the standard of
4 care?

5 A. I would -- if I were in the
6 same situation, I would not have done an
7 Avaulta product. I would have done the
8 anterior repair at the time of the sling
9 surgery.

10 Because when you're
11 repairing incontinence, if you don't
12 repair concurrent prolapse, if you find a
13 grade 2, that can affect your repair. So
14 it's not uncommon to do a prophylactic
15 either incontinence procedure or a
16 prolapse repair.

17 If Dr. Kim had repaired the
18 posterior, I would have a major problem
19 with that. But anterior compartment,
20 it's a judgment call, so I don't
21 criticize it.

22 Q. Would you agree that there
23 are risks associated with any implanted
24 product?

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1 A. Well, it depends what type
2 of implanted product we're talking about,
3 and the severity and the progressive
4 nature of them can vary tremendously.
5 But procedures do have risks.

6 Q. And we talked about some of
7 the other transvaginal mesh products
8 where you provided specific opinions in
9 other litigation.

10 Would you agree that all
11 transvaginal mesh products for pelvic
12 organ prolapse and stress urinary
13 incontinence have risks?

14 A. So I just want to make sure
15 I heard your question correctly.

16 You stated all pelvic organ
17 meshes for prolapse and slings have
18 risks; is that -- am I correct?

19 Q. Yes, essentially.

20 A. Okay.

21 Yes. To varying degrees,
22 yes, they do.

23 Q. And they all have the risk
24 of extrusion, pelvic pain and

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1 dyspareunia?

2 A. Yes, to varying degrees; as
3 long as we're still talking about pelvic
4 organ meshes and slings, they all do to
5 varying degrees.

6 Q. Would you agree that these
7 are common and well-known risks?

8 A. I agree that they are
9 common. I disagree that they are well
10 known, the true incidence is not usually
11 disclosed. It is becoming much more well
12 known since 2011.

13 Q. And if I understand your
14 report correctly, you intend to offer an
15 opinion that Dr. Kim was not advised of
16 all the potential risks?

17 A. What I'm saying is as far as
18 the level of disclosure of the known
19 risks with the Avaulta, the Avaulta Plus,
20 and the Align, that was not fully
21 disclosed, so Dr. Kim would not be able
22 to know those full risks, as I do, having
23 read internal documents, e-mails, et
24 cetera, as outlined in my general report.

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1 Q. Would you agree that Dr. Kim
2 is the better authority on what she knows
3 and what she doesn't know?

4 A. No. She knows only what she
5 knows, but she doesn't know what I know.

6 And important -- an
7 important part of that is, I've had a
8 chance to review internal documents,
9 which I'm under a confidentiality
10 agreement, so I can't discuss that, even
11 with my own colleagues, I can't
12 discuss -- or, I don't know if I can
13 discuss it so I don't. So they don't
14 know what was known at the launch of the
15 product and everything.

16 Dr. Kim knows everything she
17 knows. But, again, she doesn't know what
18 else there is out there to know. The old
19 phrase "you don't know what you don't
20 know" type of thing. That's very
21 confusing, however, it's very accurate.

22 Q. She may not know everything
23 that you know, and it's equally true that
24 you may not know everything that she

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1 knows; is that fair?

2 A. Yes, to a certain extent. I
3 have an advantage of being at a large
4 teaching institution, attend meetings
5 nationally, internationally, speak on
6 this subject, and have read internal
7 documents from, essentially, all of the
8 producers of meshes.

9 There is the chance she
10 knows something I don't. This is not a
11 criticism of her by any means, but that's
12 unlikely. So I am playing the
13 overwhelming odds I have -- I've had an
14 opportunity to know and learn more than
15 she has.

16 But, again, that's not a
17 criticism of her, by any means.

18 Q. I guess the point I'm trying
19 to get at is, if she says that she's
20 aware of the risk of extrusion, you're
21 not in a position to disagree with her;
22 is that fair?

23 A. We would have to ask her
24 what percentage. It's a vague, are you

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1 aware of the risk of a fuel pump going
2 out in a Mustang? Well, I don't know, I
3 think I do.

4 But specifics. Is she going
5 to be able to say, yeah, it's 12 to 22
6 percent, based upon e-mails that we've
7 seen from internal documents; or is she
8 going to go on the literature or is she
9 going to go off the IFU, which doesn't
10 tell us any risks?

11 So we would have to ask her
12 specifically, what are -- what percentage
13 of individuals have mesh contraction,
14 extrusion, et cetera, progressive nature.
15 And if she gave me a percentage, then I
16 would be more likely to agree or disagree
17 with your comment.

18 Q. So is it your position that
19 she can't understand the risks of the
20 product sufficiently if she doesn't know
21 the exact percentage of every potential
22 risk?

23 MS. SCARCELLO: Objection to
24 form.

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1 THE WITNESS: Yeah. With
2 patients, I feel we have an
3 obligation to tell them, you have
4 a 1 in 5 percent risk of X, Y or Z
5 complication.

6 The word significant, minor,
7 rare, don't mean anything to an
8 individual patient. That's been
9 studied; that's, you know, in some
10 of my reports. I think we have to
11 give numbers to those.

12 So Dr. Kim has a good
13 education, I don't doubt anything
14 like that. But, again, I just
15 don't think she -- she never had a
16 chance to know all that could go
17 wrong with the product.

18 BY MR. BUHR:

19 Q. Did you read her deposition
20 testimony when she talked about her
21 knowledge of the risks?

22 A. Yes.

23 Q. Do you agree that she
24 testified she was aware of the risk of

Page 62

1 extrusion?

2 A. Yes. And I also know that a
 3 doctor is not going to tell you that they
 4 did not know, because they're opening
 5 themselves up. So I agree that's what
 6 she stated.

7 Q. And she also testified that
 8 she was aware of the risk of chronic
 9 pelvic pain at the time she implanted
 10 these products?

11 A. Correct, that's what she
 12 stated.

13 Q. And she also testified that
 14 she was aware of the risk of chronic
 15 dyspareunia associated with these
 16 products at the time she implanted them
 17 in Ms. Smith?

18 A. That is -- that is what she
 19 states.

20 Q. If Plaintiff would have
 21 received a different transvaginal mesh
 22 product, would you agree that she still
 23 may have had pelvic pain and dyspareunia?
 24 MS. SCARCELLO: Object to

Page 63

1 form.

2 THE WITNESS: Well, as I've
 3 stated before, the various
 4 different mesh products all have
 5 different sets of complications,
 6 depending upon the composition of
 7 the mesh, plus or minus having a
 8 collagen -- or a, excuse me, a
 9 protein coat to them.

10 But there is significant
 11 level of risk with all of them.

12 BY MR. BUHR:

13 Q. So you're not saying that if
 14 she used a different product it would
 15 have eliminated her risk of pelvic pain
 16 or dyspareunia; is that fair?

17 A. Well, Avaulta is unique --
 18 the Avaulta Plus, excuse me. It is
 19 unique with that extra layer on it, which
 20 has never been shown to have any
 21 potential benefit.

22 So I can't state that she
 23 would have had more or less with the
 24 other ones, but the other ones don't have

Page 64

1 that coating to it. So you're not going
 2 to be lowering the risk any.

3 Q. Would you agree that a
 4 hysterectomy can cause pelvic pain and
 5 dyspareunia?

6 A. In specific locations, in
 7 varying severity and progressive nature
 8 of it, it can be associated with pelvic
 9 discomfort.

10 Q. Is that something you
 11 considered in your differential
 12 diagnosis?

13 A. Yes.

14 Q. Is that listed anywhere in
 15 your report as something you considered
 16 in your differential diagnosis?

17 A. When I review the location
 18 and the descriptions of the other
 19 doctors, and their palpation of mesh
 20 contraction, I am going to automatically
 21 rule out hysterectomy-related pain,
 22 because that's not going to cause -- or
 23 be associated with mesh contraction and
 24 palpation tenderness.

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1 Q. Is it possible that some of
 2 her pain is related to the hysterectomy?

3 A. On the anterior vault and
 4 obturator space, no.

5 It's going to be in varying
 6 degrees. So I can't completely, 100
 7 percent, rule out everything. I have to
 8 look at the data and my experience, and
 9 that's what points to the mesh.

10 Because the vaginal vault
 11 discomfort after a hysterectomy is
 12 different, it's treated differently. We
 13 have different successes with it than
 14 with the meshes. So that's why I have
 15 to -- we have to look at the totality of
 16 the patient for that answer.

17 Q. And would you agree that
 18 nowhere in your report do you discuss the
 19 hysterectomy as a possible alternative
 20 cause or how you ruled it out?

21 A. I didn't feel I needed to,
 22 because I talk about the specific mesh
 23 contraction, mesh exposure, tenderness on
 24 palpation on the anterior vault. That's

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| <p style="text-align: right;">Page 66</p> <p>1 away from where the hysterectomy was 2 performed. 3 So my experience, on a daily 4 basis dealing with women who have had 5 hysterectomies, we don't see discomfort 6 in that region. So we're talking about a 7 different region. 8 Similar, I don't talk about 9 ovarian pain or ovarian cysts, because 10 it's a different location, different 11 intensity. 12 So I don't specifically 13 state it that way, and I didn't feel I 14 needed to. 15 Q. Did you review the consent 16 form from Dr. Kim? 17 A. Yes. And I have -- I 18 believe, the consent form, I make a 19 reference to on November 30th, 2007. 20 It's on Page 11 of my report, where it 21 states, at the very last sentence -- it's 22 the middle paragraph, very last sentence, 23 and it says, A full PARQ conference was 24 held regarding the procedure.</p> | <p style="text-align: right;">Page 68</p> <p>1 devices? 2 Those are all risks included 3 on this form, correct? 4 A. Yes. This is a generic 5 form. They also have cure cancer, 6 persistent stones. This is just a 7 generic consent, not a specific one. 8 But they mentioned the 9 things you mentioned. They also talk 10 about impotence, women don't have 11 impotence. And ejaculatory dysfunction. 12 Well, women don't have that either. 13 So this is just a 14 cookie-cutter form. 15 Q. But it does include the 16 risks of dyspareunia and pelvic pain that 17 we discussed? 18 A. With no description of the 19 severity, the progressive nature of it, 20 the inability to cure it. Those things 21 are mentioned in a generic form -- 22 generic fashion, excuse me. 23 Q. Are you also intending to 24 offer an opinion on the adequacy of the</p> |
| <p style="text-align: right;">Page 67</p> <p>1 Q. Did you review the actual 2 consent form for the operation? 3 A. I don't recall -- I mean, I 4 reviewed whatever was there. I'd have to 5 go look. I don't recall the specific 6 page. I'd have to look at it. 7 MR. BUHR: Let's attach as 8 the next exhibit, I think is 9 Exhibit-7, the consent form. 10 - - - 11 (Whereupon, Exhibit 12 Elliott-7, 1/11/08 Consent Form, 13 was marked for identification.) 14 - - - 15 BY MR. BUHR: 16 Q. Do you have that in front of 17 you now, Doctor? 18 A. Yes, I do, dated January 19 11th, 2008. 20 Q. And under the risks section, 21 do you agree it discusses the risks of 22 further procedures, pain, scarring, wound 23 problems, sexual dysfunction, 24 dyspareunia, malfunction of implanted</p> | <p style="text-align: right;">Page 69</p> <p>1 IFU warnings? 2 A. For a general report, not 3 for a case-specific. I don't know how 4 that legal stuff goes. It depends what 5 I'm asked. 6 The IFU, in my opinion, is 7 incomplete, as we discussed in my general 8 deposition several years ago. 9 Q. And I don't want to re-tread 10 all that testimony. 11 But I do want to confirm 12 that specifically related to the alleged 13 injuries by Ms. Smith that it 14 specifically warns of dyspareunia and 15 scarification and contraction and 16 extrusion, correct? 17 A. Correct. That is stated in 18 there in those words that you use, 19 correct. 20 Q. <u>And did you see Dr. Kim's</u> 21 <u>testimony that she doesn't rely on</u> 22 <u>instructions for use?</u> 23 A. <u>Correct.</u> 24 Q. <u>So you're not going to offer</u></p> |

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1 an opinion in this case, then, that a
2 different warning on the IFU would have
3 made any difference to Dr. Kim; is that
4 fair?

5 A. Well, what I state is
6 regardless of what Dr. Kim relied upon,
7 the IFU has to be complete with the
8 severity, the frequency, the inability to
9 cure the problems, et cetera, as known by
10 the company.

11 Q. Right. But in terms of
12 Becky Smith's specific case, you're not
13 offering an opinion that Dr. Kim would
14 have done anything different if a
15 different warning had been provided?

16 You have to rely on Dr. Kim
17 for that, right?

18 A. Well, yeah, you're --
19 ultimately you're right. I can't state
20 what Dr. Kim would have known.

21 However, had the IFU been
22 fully complete in the severity, the
23 frequency, the inability to fix the
24 problem, Dr. Kim may have heard about

Page 71

1 that. So I can't speak -- so that would
2 be best addressed to Dr. Kim once she
3 knows all the risks of the procedure.

4 Q. And did you see her
5 testimony that she had good clinical
6 outcomes implanting both the Align and
7 the Avaulta Plus?

8 A. I saw that that's what she
9 reported.

10 Q. And you've never implanted
11 either of these products, correct?

12 A. I have chosen not to.

13 Q. Would you agree that Ms.
14 Smith initially healed well following the
15 implant surgery?

16 A. Correct, as that's what is
17 the usual.

18 Q. She did not have any
19 extrusion until approximately one year
20 after the implant; is that right?

21 A. I see, in my records,
22 February 13th, 2008. So you are correct,
23 it's a year and one month later was, I
24 believe, the -- no, excuse me, that's

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1 incorrect.

2 It's April of 2008 that I
 3 believe the records state the first mesh
 4 exposure. So a year and, what, three
 5 months, something like that.

6 Q. Well, that's one of the
 7 things I wanted to talk to you about.

8 Because I think -- so April
 9 9, 2008 is only a few months after the
 10 implant surgery, right?

11 A. You are correct.

12 Q. And so I think the date on
 13 that is wrong, and we'll pull that out in
 14 a second.

15 A. Okay.

16 Q. So in her follow-up, her
 17 first post-op visits with Dr. Kim,
 18 everything seemed to be healing properly,
 19 right?

20 A. That is correct.

21 Q. There was no sign of any
 22 mesh extrusion on January 23rd, 2008 or
 23 February 13th, 2008, right?

24 A. That is correct.

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1 Q. And she was noted to be
 2 doing extremely well by Dr. Kim, right?

3 A. That is correct.

4 Q. And at this point, the Align
 5 had corrected her stress urinary
 6 incontinence?

7 A. In the records, I believe it
 8 states something that she's doing very
 9 well without any problems. So the answer
 10 to that would be yes.

11 Q. And the Avaulta had
 12 corrected her cystocele?

13 A. Correct. Completely gone is
 14 what Dr. Kim notes on February 13th of
 15 2008.

16 Q. On what date? I'm sorry.

17 A. February 13th, 2008,
 18 cystocele, quote/unquote, what I have
 19 down here is, completely gone. That's on
 20 Page 13 of my report.

21 Q. Right.

22 And on that date, and I
 23 think it's part of, if you wanted to turn
 24 to the records, part of Exhibit-5, and

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| <p style="text-align: right;">Page 74</p> <p>1 Dr. Kim notes that the anterior vaginal 2 wall has healed very nicely; is that 3 right? 4 A. I don't have those records. 5 But that's, from my recollection, 6 correct. 7 Q. Then turning to this April 8 9th, 2008 note that you have of possible 9 mesh extrusion. And that would be on 10 Exhibit-5, ending in Bates number 11. 11 MS. SCARCELLO: Exhibit-5. 12 THE WITNESS: I'm sorry, 13 Exhibit-5. I thought you were 14 going to hand me something, turns 15 out I already have it. 16 You said Exhibit-5? 17 MR. BUHR: Yes. 18 THE WITNESS: Okay, I'm 19 sorry. And then Bates number? 20 MR. BUHR: 11. 21 THE WITNESS: Okay, I'm 22 there. 23 BY MR. BUHR: 24 Q. So is this the record you're</p> | <p style="text-align: right;">Page 76</p> <p>1 4/1/9 -- I mean, I don't know. If we did 2 1 -- 3 Q. And I think we do have 4 another copy of this that was in the 5 hospital records. 6 MR. BUHR: Can we attach it 7 as the next exhibit? Is that 8 Exhibit-8, then? 9 MS. GRIFFIN: Correct. 10 - - - 11 (Whereupon, Exhibit 12 Elliott-8, Hospital Record, was 13 marked for identification.) 14 - - - 15 THE WITNESS: If you look 16 down in the history of present 17 illness, 49-year-old female 18 underwent cystocele/Avaulta 19 repair, 1/15/08. Now with mesh 20 extrusion. 21 So, I mean, it -- I'm going 22 to hold with 4/9/08, unless you 23 have something to be definitive. 24 I'm not going to be --</p> |
| <p style="text-align: right;">Page 75</p> <p>1 referring to in your report for April 2 9th, 2008? 3 A. Correct. 4 Q. Is it possible that that 5 handwritten date is actually January 6 19th, 2008 -- or 2009, rather, and that 7 it was a mistake that's often made in 8 January by writing the prior year, 2008? 9 A. So you're saying -- 10 Q. 1/19 instead of 4/9? 11 A. I'm not a, what do you call 12 it, writer expert. I'm just looking at 13 it. I see a 4 and then a 1 with a little 14 slash up, 9, and the slash and up again, 15 08. 16 To me it looks like 4/1 -- I 17 mean, we can't be definitive. But, I 18 mean, it looks like my date of April 9th, 19 and you're telling -- you're suggesting 20 what again? 1 -- 21 Q. 1/19 and that they 22 mistakenly wrote 2008 instead of 2009? 23 A. Well, I -- I don't want to 24 be difficult. To me, it looks like a</p> | <p style="text-align: right;">Page 77</p> <p>1 BY MR. BUHR: 2 Q. And the plan there is 3 excision of the mesh, right? 4 A. Correct. 5 Q. And you're not aware of any 6 excision of the mesh at that time, in 7 April of 2008? 8 A. I'm not aware of any, no. 9 Q. And this is written by Dr. 10 Kim's physician assistant; is that right? 11 A. I don't know whose assistant 12 it is, but it's a physician assistant. 13 MR. BUHR: Did we mark 14 Exhibit-8? 15 MS. GRIFFIN: We did, yes. 16 BY MR. BUHR: 17 Q. And you see, Doctor, at the 18 top there, how it lists typewritten, 19 1/19/2009? 20 A. Sure. 21 Q. So just keep that in mind 22 and let me know in a minute if the timing 23 of January 19th, 2009 makes more sense 24 with the subsequent reports by Ms. -- by</p> |

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| <p style="text-align: right;">Page 78</p> <p>1 Dr. Kim.</p> <p>2 A. Well --</p> <p>3 Q. And so, specifically, on --</p> <p>4 go ahead.</p> <p>5 A. I'm sorry, I did interrupt</p> <p>6 you. That was my fault. My bad.</p> <p>7 Q. So specifically on January</p> <p>8 16th, 2009 she returned to see Dr. Kim,</p> <p>9 right?</p> <p>10 A. Yes.</p> <p>11 Q. And even according to your</p> <p>12 report, it says, With a new complaint of</p> <p>13 vaginal mesh exposure beginning roughly</p> <p>14 one month prior.</p> <p>15 A. Yeah, that's what -- yeah, I</p> <p>16 must have gotten that from the records.</p> <p>17 Q. Right. So this is what</p> <p>18 she's reporting to Dr. Kim on January</p> <p>19 16th, 2009. And you even quote, in your</p> <p>20 report, About a month ago, her husband</p> <p>21 noticed some evidence of mesh during</p> <p>22 sexual intercourse, and this is becoming</p> <p>23 progressively worse.</p> <p>24 Is that right?</p> | <p style="text-align: right;">Page 80</p> <p>1 2008, where she had a plan of mesh</p> <p>2 excision?</p> <p>3 MS. SCARCELLO: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: Yeah, there's</p> <p>6 a conflict there.</p> <p>7 First of all, this is not to</p> <p>8 be picky, it's a physician</p> <p>9 assistant, so it's not a</p> <p>10 physician.</p> <p>11 But, yeah, there is -- there</p> <p>12 is a discrepancy as far as the</p> <p>13 dates go. I won't argue with</p> <p>14 that.</p> <p>15 BY MR. BUHR:</p> <p>16 <u>Q. So at least according to Dr.</u></p> <p>17 <u>Kim's report, she did not feel anything</u></p> <p>18 <u>until about a month prior to this January</u></p> <p>19 <u>16th, 2009 report, correct?</u></p> <p>20 <u>A. Correct, that's what Dr. Kim</u></p> <p>21 <u>reports.</u></p> <p>22 Q. And then Dr. Kim recommended</p> <p>23 mesh excision, which took place a few</p> <p>24 days later on January 20th, 2009?</p> |
| <p style="text-align: right;">Page 79</p> <p>1 A. Yeah. That's what the</p> <p>2 report says, yes.</p> <p>3 Q. And if you actually look at</p> <p>4 that report, which is at -- again, it's</p> <p>5 on Exhibit-5, Bates number ending in 07.</p> <p>6 Do you have Bates number 7</p> <p>7 in front of you?</p> <p>8 A. Yes, I do.</p> <p>9 Q. So there in that first</p> <p>10 paragraph is the language that's quoted</p> <p>11 in your report that I just read.</p> <p>12 And the subsequent sentence</p> <p>13 says, The patient states that up until a</p> <p>14 month ago, she did not feel anything at</p> <p>15 all.</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. So would you agree that that</p> <p>19 conflicts with the suggestion that the</p> <p>20 prior report, from Dr. Wyndham, was on</p> <p>21 January -- sorry. Let me start over.</p> <p>22 Would you agree that that</p> <p>23 conflicts with the suggestion that the</p> <p>24 report from Dr. Wyndham was April 9th,</p> | <p style="text-align: right;">Page 81</p> <p>1 A. Correct.</p> <p>2 Q. And had she stopped using</p> <p>3 her Estrace cream at this point?</p> <p>4 A. I believe I saw a mention of</p> <p>5 that.</p> <p>6 Q. Can that increase your risk</p> <p>7 for mesh extrusion?</p> <p>8 A. Well, I'm not aware of</p> <p>9 anywhere it states that with the Avaulta</p> <p>10 product you have to be on it permanently.</p> <p>11 Estrogen can potentially</p> <p>12 help reduce that risk. But, again, I'm</p> <p>13 not -- I've never seen where you're</p> <p>14 supposed to be on it.</p> <p>15 Q. No. But Dr. Kim had</p> <p>16 prescribed estrogen cream following the</p> <p>17 implant, correct?</p> <p>18 A. Correct. And it's not</p> <p>19 uncommon for women not to like it for</p> <p>20 some reason, concerns about breast</p> <p>21 cancer, blood clots and those types of</p> <p>22 things, to stop taking -- or it's just</p> <p>23 plain messy. But he did prescribe it</p> <p>24 afterwards.</p> |

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| <p style="text-align: right;">Page 82</p> <p>1 Q. And having a hysterectomy at 2 the same time, would she have had 3 postmenopausal changes after the surgery? 4 A. No. 5 Q. Was she found to have 6 vaginal atrophy and thinning tissue? 7 A. Yes. But she still has her 8 ovaries in place. They were not removed, 9 by her request. So we don't know the 10 volume of estrogen being produced. A 11 49-year-old female, you don't know. 12 Q. But Dr. Kim recommended 13 restarting the Estrace cream on January 14 16th, 2009, based on her complaints; is 15 that right? 16 A. Yeah. As I have in my -- on 17 Page 13, third paragraph, Dr. Kim 18 recommended restarting Estrace cream. 19 But because of the extent of the erosion, 20 I think this needs to be treated 21 surgically, end quote. 22 Q. Are there factors that can 23 increase a woman's risk for having mesh 24 extrusion?</p> | <p style="text-align: right;">Page 84</p> <p>1 smoking were a risk factor, then that has 2 to be in the IFU, and it's nowhere. At 3 least I haven't seen it. We can pull it 4 out and show it, and I'll change my 5 opinion. But I'm not aware of that. 6 In fact, some will say the 7 mesh kits are better because a smoker has 8 a chronic cough, so it needs to be a 9 stronger repair. So I'd have to -- I'd 10 have to disagree with you. 11 Q. I guess my question is more 12 that smoking can have an effect on a 13 patient's tissue quality, right? 14 A. Yes. 15 Q. And if a patient has poor 16 tissue quality, that can increase their 17 likelihood for something like extrusion; 18 is that right? 19 A. I suppose, in theory, that 20 is possible. 21 As far as I know, Ms. Smith 22 is a nonsmoker, so it's a moot point 23 here. But, again, if meshes have an 24 increased risk of complication like</p> |
| <p style="text-align: right;">Page 83</p> <p>1 A. I've never read in the IFU 2 factors, which if they are known, they 3 should be in there. 4 I have seen internal 5 documents that if you have a hysterectomy 6 at the same time, you're increasing your 7 risk for exposure. But, again, that's 8 not in the IFU. 9 Advanced age probably would 10 increase it. But, again, that's not in 11 the IFU. And presence of an infection 12 would do it. 13 So there are going to be 14 factors there. But I'm not aware of the 15 company disclosing that they knew of 16 factors. If they did, they should report 17 it. 18 Q. Well, there's also certain 19 factors that are generally known in the 20 medical community. 21 For example, would you agree 22 that smoking can increase the risk of 23 extrusion? 24 A. Excellent point. No. If</p> | <p style="text-align: right;">Page 85</p> <p>1 exposure with smoking, then that's got to 2 be on the IFU. 3 Q. Turning more specifically to 4 Ms. Smith, if she has thinning of the 5 vaginal tissue and vaginal atrophy, can 6 that increase her risk for extrusion? 7 A. Well, we're talking 8 theoretically here. But the presence of 9 the mesh inside of her body will cause 10 thinning of the vaginal tissue and 11 atrophy appearance, because it is slowly 12 causing a necrosis. So you can't say 13 which comes first. 14 She's, at this point in 15 time, a 49-year-old female. 16 Theoretically, she should be producing 17 estrogen still. Her ovaries are still in 18 place. So I can't completely agree with 19 you on what's coming first. 20 Prior to her surgery, there 21 was -- one year prior, there was no 22 indication of vaginal atrophy. Then she 23 has surgery, a mesh is put in with 24 foreign body reaction, inflammation,</p> |

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| <p style="text-align: right;">Page 86</p> <p>1 she's getting exposure, which means</p> <p>2 thinning out. So I would say a logical</p> <p>3 conclusion, that's due to the presence of</p> <p>4 the mesh, not due to her.</p> <p>5 Q. I think my question was, if</p> <p>6 a patient has vaginal atrophy, can that</p> <p>7 increase their risk for extrusion?</p> <p>8 A. I know -- I hear what you're</p> <p>9 saying.</p> <p>10 And not to be difficult,</p> <p>11 we're talking about a theoretical</p> <p>12 patient, how severe that is, and we're</p> <p>13 not talking about Ms. Smith.</p> <p>14 So we would have to have a</p> <p>15 specific individual we're talking about</p> <p>16 how bad this atrophy is. And, again,</p> <p>17 let's say you are correct, then that's</p> <p>18 not on the IFU and it's not warned at</p> <p>19 all. So if that is a known risk, that</p> <p>20 will be very important to know.</p> <p>21 Q. And so are you agreeing with</p> <p>22 me that it's a factor to consider?</p> <p>23 A. Vaginal atrophy would be,</p> <p>24 definitely, something that you would want</p> | <p style="text-align: right;">Page 88</p> <p>1 going to happen in over one year's time.</p> <p>2 So, then, the culprit becomes the</p> <p>3 presence of the Avaulta and the</p> <p>4 inflammatory process it causes.</p> <p>5 Q. In the list of examples of</p> <p>6 your differential diagnosis on Page 4 and</p> <p>7 5, you do not list vaginal atrophy or</p> <p>8 postmenopausal changes in that list; is</p> <p>9 that right?</p> <p>10 A. It is not listed there, no.</p> <p>11 Q. In the excision procedure</p> <p>12 performed by Dr. Kim, she was able to</p> <p>13 remove the exposed mesh quite easily,</p> <p>14 right?</p> <p>15 A. Yes, she uses those words,</p> <p>16 "quite easily."</p> <p>17 Q. And I believe you said</p> <p>18 earlier that this extrusion relates to</p> <p>19 the Avaulta and not the Align; is that</p> <p>20 right?</p> <p>21 A. I'd have to go back and look</p> <p>22 at the specific operative note. But, as</p> <p>23 I recall, this is specifically due to the</p> <p>24 Avaulta, where it is located. It was</p> |
| <p style="text-align: right;">Page 87</p> <p>1 to consider if it's severe prior to</p> <p>2 putting in a mesh.</p> <p>3 You don't have to worry</p> <p>4 about that with nonmesh repairs. But in</p> <p>5 a mesh repair, you would. And it would</p> <p>6 be a woman's right to know that her body</p> <p>7 could be permanently harmed if this</p> <p>8 product is put in. So, for me, it</p> <p>9 becomes under a woman's rights issue.</p> <p>10 Q. Did you consider vaginal</p> <p>11 atrophy in your differential diagnosis?</p> <p>12 A. Yes, I did. By the reasons</p> <p>13 I have already explained in the last</p> <p>14 couple of questions ago; 49 year old, she</p> <p>15 was 48, I believe, at the time of her</p> <p>16 surgery, she was premenopausal, her</p> <p>17 ovaries are still in, there's no vaginal</p> <p>18 atrophy prior to her surgery.</p> <p>19 One year later, with her</p> <p>20 ovaries still in place, we have mesh</p> <p>21 exposure, thinning and atrophy. And in</p> <p>22 my opinion, based upon my experience,</p> <p>23 vaginal atrophy due to menopause takes</p> <p>24 years and years to develop, it's not</p> | <p style="text-align: right;">Page 89</p> <p>1 well away from the Align.</p> <p>2 Q. And she healed well</p> <p>3 following this procedure; is that right?</p> <p>4 A. Correct.</p> <p>5 Q. The anterior vaginal wall</p> <p>6 completely healed?</p> <p>7 A. Yes. As of the note, April</p> <p>8 16th, 2009, I believe she uses that word,</p> <p>9 The anterior vaginal wall has healed up</p> <p>10 completely. I do not feel any mesh</p> <p>11 exposure -- extrusion. End quote.</p> <p>12 Q. And Dr. Kim prescribed</p> <p>13 Vagifem tablets on that date?</p> <p>14 A. I did not make a record of</p> <p>15 that. I would have to see the record.</p> <p>16 Q. I think it's the first page</p> <p>17 on Exhibit-5.</p> <p>18 A. He gave -- she gave Ms.</p> <p>19 Smith samples of Vagifem. So she didn't</p> <p>20 give a prescription, she gave some</p> <p>21 samples.</p> <p>22 Q. And what is Vagifem, for the</p> <p>23 record?</p> <p>24 A. Vagifems are actually</p> |

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1 estrogen tablets that go into the vagina.
 2 They are usually, for most patients,
 3 easier to use. They are cleaner. The
 4 Premarin cream tends to be quite messy,
 5 has an applicator that women don't like.

6 So Vagifem is just an easier
 7 way to insert the estrogen. The problem
 8 with it is, it doesn't necessarily stay
 9 where you want it to go. But just think
 10 of it as a different form of estrogen.

11 Q. And do you have an
 12 understanding as to why Dr. Kim was
 13 prescribing estrogen at this time?

14 MS. SCARCELLO: Object to
 15 form.

16 You can answer.

17 THE WITNESS: Trying to heal
 18 up the vaginal wall or continue to
 19 heal it up.

20 BY MR. BUHR:

21 Q. Is that something that is
 22 needed in order to heal the vaginal wall?

23 A. Not necessarily, but she was
 24 having trouble with the Estrace cream, it

Page 91

1 was causing irritation. So that could be
 2 part of the reason why she stopped it
 3 before.

4 Q. And Dr. Kim obviously felt
 5 like it was important for her to have
 6 some estrogen cream or estrogen tablets?

7 A. That would be the standard
 8 party line of what you do after a mesh
 9 exposure, is to give vaginal estrogen.

10 But, again, some women can't
 11 tolerate it, for multiple different
 12 reasons. And if she had trouble with the
 13 Estrace cream, which is just a form of
 14 Premarin cream, she could also have
 15 trouble with the Vagifem, because, it's,
 16 again, the same thing, it's just
 17 estrogen.

18 Q. And would you agree at this
 19 point in the records there's no
 20 documented complaint of pelvic pain or
 21 dyspareunia?

22 A. For her, Ms. Smith, there
 23 was no documented pelvic pain or
 24 dyspareunia. Her partner had noticed

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1 discomfort prior.

2 Q. And would you agree that
 3 the -- she did not complain to a doctor
 4 about any problems after this until 2017?

5 A. I did not have anything in
 6 the records from 2009 until March 21,
 7 2017. So I agree with you.

8 Q. And, in fact, during that
 9 period of time, she saw Ms. Hoth for her
 10 annual exams and reported no complaints
 11 of dyspareunia; is that right?

12 A. That is correct.

13 Q. You reference an August 8th,
 14 2013 record from Ms. Hoth where she had
 15 bothersome arm pain but no other
 16 complaints on that day.

17 A. That is correct.

18 Q. Did you see that Ms. Smith
 19 actually asked Ms. Hoth on that day about
 20 advertisements for vaginal mesh
 21 litigation?

22 A. I remember seeing a
 23 reference about that somewhere. I
 24 don't -- I'd have to see the specific

Page 93

1 note.

2 MR. BUHR: Let's attach as,
 3 I believe it's Exhibit-9 we're on
 4 now, the record from Ms. Hoth on
 5 February 16th -- actually, no.
 6 Let's attach the record from
 7 August 8th, 2013.

8 - - -
 9 (Whereupon, Exhibit
 10 Elliott-9, 8/8/13 Hoth Note, was
 11 marked for identification.)

12 - - -
 13 THE WITNESS: I have it.

14 BY MR. BUHR:

15 Q. And if you'd go to the Bates
 16 number that ends in 08.

17 A. Okay. I'm there.

18 Q. The top of the next page.

19 But has no other complaints
 20 today. Although has a mesh and is
 21 concerned about this, given the current
 22 TV ads for, Do you have a mesh, you could
 23 be due compensation. Has had sling and
 24 had mesh put in when she had the

Page 94

1 hysterectomy. And then they had to trim
2 it up.

3 Q. Do you see that?

4 A. Yes, I do.

5 Q. So she was specifically
6 asking her doctor about concerns about
7 the mesh, but at this point she was not
8 complaining of any symptoms of pelvic
9 pain or dyspareunia or extrusion or
10 anything like that, right?

11 A. You are correct.

12 Q. Just to be clear, your
13 report includes a reference to a February
14 16th, 2012 report?

15 A. Yes.

16 Q. Where you have a reference
17 to pelvic pain with exercise.

18 A. Correct.

19 Q. You're not offering an
20 opinion that that pain is anywhere
21 related to the mesh at this point; is
22 that right?

23 A. I'm just stating what the
24 records stated. The record,

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1 unfortunately, and what I deal with all
2 the time, is incomplete. It just makes a
3 reference to it.

4 So I put it down as
5 documentation. But I'm not making a
6 conclusion at that point in time.

7 Q. So at what point in time are
8 you making a conclusion that she's having
9 pain related to the mesh? Is that in
10 March 2017?

11 A. Well, I have to go off of
12 the records. All I saw in there, and we
13 can maybe go to that February 16th, 2012
14 note, if it's there, and that was just in
15 there. That's all it stated.

16 If it stated more, like it's
17 lifting or a pelvic exam confirms it --
18 I'm just stating that it is there for
19 completeness sake. But I'm not stating
20 that is due to mesh. All I've got is a
21 statement there. That's all I've got.

22 So, like, for a differential
23 diagnosis, I don't have enough
24 information to make a conclusion. I'm

Page 96

1 just documenting that that's what's in
2 the records.

3 Q. Okay. Fair enough.

4 MR. BUHR: And let's for
5 completeness just go ahead and
6 attach that record as Exhibit-10.

7 - - -

8 (Whereupon, Exhibit
9 Elliott-10, 2/16/12 Hoth Office
10 Visit, was marked for
11 identification.)

12 - - -

13 BY MR. BUHR:

14 Q. Do you have that in front of
15 you now, Doctor?

16 A. Yes. The first page is
17 2017, so it must be before that.

18 Q. I think that's the printing
19 date.

20 If you look on the left
21 side, it should be 2/16/2012 office visit
22 with Ms. Hoth.

23 A. I have February 16th of '12.
24 Is that --

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1 Q. Yes.

2 A. Yes, I have it then.

3 Q. So towards the bottom of
4 that page, it says, Is pain an issue
5 needing to be addressed today? And it
6 says, No.

7 Right?

8 A. Yeah, that's what it states.

9 Q. And then on Bates number
10 ending in 225, about halfway down the
11 page, it has a list for dyspareunia and
12 then it says no.

13 Do you see that?

14 A. Correct, that's what it
15 states.

16 Q. And then a little bit
17 further down is what I believe you were
18 referring to in your record, under
19 musculoskeletal, where she says, Pelvis
20 with exercise hurts and put back out this
21 Christmas.

22 Is that what you were
23 referring to in your report?

24 A. Correct.

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| <p style="text-align: right;">Page 98</p> <p>1 Q. And then if you go onto the 2 next page -- well, she does -- she does 3 an exam? 4 A. Correct. 5 - - - 6 (Whereupon, a discussion off 7 the record occurred.) 8 - - - 9 BY MR. BUHR: 10 Q. And her assessment for the 11 GYN assessment is normal exam, correct? 12 A. Correct. Note, With 13 fullness, no masses or tenderness. A 14 negative exam. 15 Q. So then at this point, it's 16 pretty clear she is not complaining of 17 any pain or dyspareunia related to the 18 mesh, correct? 19 A. Well, as before, she has 20 pelvic -- quote/unquote, Pelvis with 21 exercise hurts and puts -- and put back 22 out this Christmas. 23 So, again, I am not stating 24 it's due to the mesh. I'm not</p> | <p style="text-align: right;">Page 100</p> <p>1 It's not going to change 2 pain. It's for a vaginal extrusion. So 3 I can't vouch for the correctness of that 4 decision. 5 Q. And you state in your 6 report, Said will trial for two months 7 and see if it provides relief. 8 A. Correct. And vaginal 9 estrogen in two months is not going to do 10 any good, you need much longer than that. 11 So that's, reading between 12 the lines, somebody who doesn't deal with 13 meshes. It's not a criticism. 14 Q. She had no -- sorry? 15 A. I interrupted. 16 Q. She had no evidence of mesh 17 extrusion at this time; is that right? 18 A. All I have down is, on Page 19 14, during the vaginal exam, Ms. Cool 20 noted that the, quote, bladder sling 21 palpable anteriorly during bimanual exam, 22 end quote. 23 So there's -- I don't know 24 what that means. Is that exposure or</p> |
| <p style="text-align: right;">Page 99</p> <p>1 eliminating mesh as an option. I'm not 2 including it. It's just a statement 3 that's there. 4 But in the physical exam, 5 there was no pain on exam. 6 Q. So, then, in March of 2017, 7 as we've discussed, is her first real 8 complaint of pelvic pain and dyspareunia 9 related to the mesh. 10 And she saw a doctor -- or, 11 sorry, a nurse practitioner, Shawn Cool; 12 is that right? 13 A. Correct. 14 Q. And this doctor also -- or 15 this nurse practitioner also advised on 16 starting vaginal estrogen cream; is that 17 right? 18 A. Correct. 19 Q. And why would she prescribe 20 that at the time? 21 A. Well, I can't speak for this 22 individual, a nurse practitioner. It's 23 pretty much the standard thing, knee-jerk 24 response, to give estrogen.</p> | <p style="text-align: right;">Page 101</p> <p>1 what? We can't put a lot into that, 2 because this is a nurse practitioner not 3 experienced in this. 4 So I can't say, is that 5 exposure? Is that just that you could 6 feel the scarring and the contraction? I 7 put that in there for thoroughness sake. 8 She needs -- the patient, 9 Ms. Smith, needs somebody more advanced 10 to be able to give us specifics if we 11 want accuracy. 12 Q. Do you know if she continued 13 using the estrogen cream? 14 A. I don't recall. I 15 remember -- I know she's used it on and 16 off. But, again, she had vaginal 17 irritation with it, so I don't -- I can't 18 say how well she used it. 19 Q. In terms of your 20 differential with respect to dyspareunia 21 and the pelvic pain, did you consider the 22 vaginal atrophy that she was having at 23 this point? 24 A. Yeah. Vaginal atrophy will</p> |

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| <p style="text-align: right;">Page 102</p> <p>1 cause diffuse -- can cause diffuse 2 irritation of the vagina, thinning of the 3 vagina. It's not going to cause specific 4 pinpoint pain or palpation of a mesh 5 causing pain. 6 It can cause some burning 7 with sexual activity. It does not cause, 8 usually, discomfort with normal, daily 9 activities. 10 So that is always in the 11 differential diagnosis. I ruled it out 12 in this one, again, because the suspicion 13 on exam of palpating the sling. 14 Q. Are you saying that vaginal 15 atrophy isn't playing any type of role 16 here? 17 A. It can be a very mild 18 complicating factor. If vaginal atrophy 19 is the source for the problem, estrogen 20 can help repair it. But it's not going 21 to cause pain along a mesh. 22 Q. But you can't rule it out 23 completely as a mild complicating factor? 24 A. I can rule it out 99.9</p> | <p style="text-align: right;">Page 104</p> <p>1 Denam, Mary Denam, on -- unfortunately, I 2 don't think I have a date here on this 3 one. Page 15, starting with the bottom 4 paragraph -- for some reason I don't have 5 a date on that, there needs to be a 6 date -- there's no mention of a posterior 7 prolapse. 8 MR. BUHR: We've been going 9 for a while, Doctor. How about we 10 take a five-minute break and then 11 come back and finish up with the 12 rest? 13 THE WITNESS: I'm good, if 14 you want to keep going. 15 MR. BUHR: I'd like a 16 five-minute break, if you don't 17 mind. 18 THE WITNESS: That's no 19 problem. 20 VIDEO TECHNICIAN: We're 21 going off record. The time is 22 3:14. 23 - - - 24 (Whereupon, a brief recess</p> |
| <p style="text-align: right;">Page 103</p> <p>1 percent, based upon my experience, my 2 attendance at national/international 3 meetings, giving lectures on the subject, 4 and daily exposure to patients. 5 Q. Did she have a rectocele at 6 this point? Well, let me rephrase that. 7 She had a mild rectocele at 8 the time of the implant; had the 9 rectocele progressed? 10 A. I'd have to go over -- the 11 notes are classic for a general 12 practitioner family practice-type, but 13 they don't give specifics. 14 The first note with the 15 nurse practitioner, in March of '17, does 16 not tell me anything of specifics of 17 concurrent prolapse. 18 Follow-up note with the same 19 practitioner, August 13th, 2018, does not 20 state of the posterior -- it does not 21 state of any prolapse, which is an 22 incomplete note and not acceptable with 23 advanced-level-of-care individual. 24 And the physical exam by Dr.</p> | <p style="text-align: right;">Page 105</p> <p>1 was taken.) 2 - - - 3 VIDEO TECHNICIAN: We're 4 going back on the record. 5 Beginning of Media File 2. The 6 time is 3:24. 7 BY MR. BUHR: 8 Q. I'd like to attach some of 9 the records from The Oregon Clinic as 10 Exhibit-11, I believe. These are the 11 Bates numbers that end in 7 -- well, 12 sorry, from 11 to 22. 13 - - - 14 (Whereupon, Exhibit 15 Elliott-11, The Oregon Clinic 16 Records, was marked for 17 identification.) 18 - - - 19 THE WITNESS: Okay, I have 20 it. 21 BY MR. BUHR: 22 Q. If you go to Bates number 23 that ends in 17, it should be an office 24 visit with Lindsey Waugh, if I'm</p> |

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| <p style="text-align: right;">Page 106</p> <p>1 pronouncing that correctly, dated August 2 23rd, 2018.</p> <p>3 A. Okay. I'm there.</p> <p>4 Q. And this is one of the 5 reports that you reference in -- or one 6 of the records you reference in your 7 report on Page 15; is that right?</p> <p>8 A. That is correct.</p> <p>9 Q. And it states at this point 10 that she's having a constant, dull pain 11 with intercourse?</p> <p>12 A. Well, constant, dull pain, 13 especially with intercourse.</p> <p>14 Q. And it notes that the pain 15 level is 2 on a scale of 1 to 10.</p> <p>16 Would you agree with me that 17 that's not severe pain that you describe 18 in your report?</p> <p>19 A. Well, on a scale of 1 to 10, 20 it doesn't rank up as severe. It's worse 21 than a 1, but it is not in the highest 22 scores, obviously.</p> <p>23 Q. And then in the third 24 paragraph on that page, it says, The</p> | <p style="text-align: right;">Page 108</p> <p>1 she does not use it despite what was 2 given to her.</p> <p>3 Q. And if you can turn to the 4 notes of physical exam on Bates number 5 21.</p> <p>6 A. Okay. I'm there.</p> <p>7 Q. So the external genitalia, 8 it notes, Postmenopausal with moderate 9 atrophy; is that right?</p> <p>10 A. Correct.</p> <p>11 Q. And then, actually, inside 12 the vagina is postmenopausal atrophic 13 appearance; is that right?</p> <p>14 A. That's what it states.</p> <p>15 Q. And the estrogen cream would 16 be helpful for that type of atrophy, 17 would you agree with that?</p> <p>18 A. If she's making the right 19 call that it's due to atrophy, that would 20 theoretically help, if she can tolerate 21 it.</p> <p>22 Q. And then it notes, The 23 posterior compartment prolapse to level 24 of the hymenal ring.</p> |
| <p style="text-align: right;">Page 107</p> <p>1 sling is working great, no leaking.</p> <p>2 So her stress urinary 3 incontinence has still been corrected by 4 the Align product, right?</p> <p>5 A. That is correct.</p> <p>6 Q. Do you see the note that 7 says, Does not use estrogen cream on a 8 regular basis?</p> <p>9 A. Correct.</p> <p>10 Q. And this is despite being 11 prescribed estrogen cream the prior year 12 by Nurse Practitioner Cool, right?</p> <p>13 A. That is correct.</p> <p>14 The vaginal estrogen would 15 be for the health of the vaginal tissue, 16 for lubrication during sexual activity. 17 And so it states, And does not have 18 issues with vaginal lubrication.</p> <p>19 So the only reason to give 20 her -- or for her to take it would be for 21 a mesh complication. And she's not 22 having exposure, so there's really no 23 reason to be on it.</p> <p>24 But that's what it states,</p> | <p style="text-align: right;">Page 109</p> <p>1 A. Correct.</p> <p>2 Q. What stage prolapse is that?</p> <p>3 A. Stage 2.</p> <p>4 Q. It's a stage 2 rectocele she 5 has now, right?</p> <p>6 A. Correct. It's to the level 7 of the hymenal ring. It doesn't say it 8 goes beyond. That would be a stage 2.</p> <p>9 Q. And under impression it 10 notes that she has symptomatic posterior 11 compartment prolapse.</p> <p>12 What symptoms was she having 13 related to that prolapse?</p> <p>14 A. Well, from the note, she 15 denies feeling a vaginal bulge. She does 16 feel some pressure towards her rectum.</p> <p>17 So that would be the 18 posterior prolapse symptoms.</p> <p>19 Q. Can posterior prolapse cause 20 pelvic pain and dyspareunia?</p> <p>21 A. It can cause a sense of 22 fullness and pressure, but it would not 23 cause a tender-to-palpation issue like 24 she had on her exam.</p> |

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| <p style="text-align: right;">Page 110</p> <p>1 Q. And that rectocele hasn't</p> <p>2 been repaired at any time subsequent to</p> <p>3 this; is that right?</p> <p>4 A. I have not reviewed any</p> <p>5 records stating that it has been</p> <p>6 repaired, correct.</p> <p>7 Q. So she would still be</p> <p>8 expected to have symptoms related to that</p> <p>9 posterior prolapse, right?</p> <p>10 A. Prolapse symptoms tend not</p> <p>11 to go away, so I would expect for her to</p> <p>12 still have symptoms.</p> <p>13 Q. And even though she states</p> <p>14 that she doesn't believe she has any</p> <p>15 trouble with lubrication, vaginal atrophy</p> <p>16 can cause painful sex, right?</p> <p>17 A. It can cause irritation and</p> <p>18 burning with sexual activity, which is</p> <p>19 usually treated with a lubricant -- or</p> <p>20 can be successfully treated with</p> <p>21 lubricant or the vaginal estrogen.</p> <p>22 But, again, it won't cause</p> <p>23 tender-to-palpation or specific pinpoint</p> <p>24 pain.</p> | <p style="text-align: right;">Page 112</p> <p>1 that she was on vaginal estrogen for a</p> <p>2 period of time but not long-term --</p> <p>3 A. Correct.</p> <p>4 Q. -- correct?</p> <p>5 A. Yes.</p> <p>6 Q. And she has not had any</p> <p>7 pelvic floor physical therapy?</p> <p>8 A. Correct.</p> <p>9 Q. Is that something that can</p> <p>10 help with pelvic pain?</p> <p>11 A. It depends what type of</p> <p>12 pelvic pain it is. In my experience,</p> <p>13 pelvic floor myalgia which is de novo,</p> <p>14 you can have some benefit from it.</p> <p>15 Secondary to mesh, I have</p> <p>16 never had a patient get significant</p> <p>17 reduction of pain with physical therapy.</p> <p>18 Q. Would you agree that Dr.</p> <p>19 Denman felt that physical therapy was an</p> <p>20 important part of her plan for Ms. Smith?</p> <p>21 A. Well, not really, because</p> <p>22 she recommended going to surgery fairly</p> <p>23 soon afterwards. So it was not a serious</p> <p>24 consideration. She gives it as an</p> |
| <p style="text-align: right;">Page 111</p> <p>1 Q. There is no evidence of mesh</p> <p>2 extrusion at this visit, right?</p> <p>3 A. There is no report of mesh</p> <p>4 exposure.</p> <p>5 Q. And then she's referred to</p> <p>6 Denman.</p> <p>7 And I think that's what you</p> <p>8 were referring to prior to our break?</p> <p>9 A. Correct.</p> <p>10 Q. And that's when Dr. Denman</p> <p>11 notes that she has pelvic pain with</p> <p>12 intercourse and feels a bulge with and</p> <p>13 after a bowel movement, right?</p> <p>14 A. Correct.</p> <p>15 Q. And so could some of that be</p> <p>16 related to her rectocele?</p> <p>17 A. That's why you would need</p> <p>18 the physical exam to confirm it. A</p> <p>19 physical exam will tell you if she has</p> <p>20 the rectocele, palpation in certain</p> <p>21 areas, pelvic floor, et cetera.</p> <p>22 Again, that's why the</p> <p>23 physical exam is so important.</p> <p>24 Q. And Dr. Denman even notes</p> | <p style="text-align: right;">Page 113</p> <p>1 option.</p> <p>2 Q. Let's turn to Dr. Denman's</p> <p>3 report from August 29th, 2018, which is</p> <p>4 actually part of that last exhibit.</p> <p>5 Do you have that record in</p> <p>6 front of you?</p> <p>7 A. Yes, I do. You're talking</p> <p>8 Exhibit-11?</p> <p>9 MS. GRIFFIN: Correct.</p> <p>10 MR. BUHR: Yes.</p> <p>11 THE WITNESS: And what</p> <p>12 page -- I'm sorry, Bates number?</p> <p>13 MR. BUHR: The Bates number</p> <p>14 11. So the first page of that</p> <p>15 exhibit.</p> <p>16 THE WITNESS: I'm there.</p> <p>17 BY MR. BUHR:</p> <p>18 Q. So about halfway through the</p> <p>19 paragraph, under plan, it says, Discussed</p> <p>20 need for PT -- which I assume is physical</p> <p>21 therapy -- after surgery to help decrease</p> <p>22 scar tissue formation as well as decrease</p> <p>23 pain.</p> <p>24 A. Correct. That's what she</p> |

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| <p style="text-align: right;">Page 114</p> <p>1 states.</p> <p>2 Q. Do you agree that that's --</p> <p>3 do you agree that that's part of her</p> <p>4 plan, then, and she thought that would</p> <p>5 help?</p> <p>6 A. Well, she discusses it after</p> <p>7 surgery. It won't have any bearing on</p> <p>8 scar tissue, but it may help decrease the</p> <p>9 pain. In my experience, it does not.</p> <p>10 Q. Will it help --</p> <p>11 A. I'm sorry.</p> <p>12 Q. Would it help decrease the</p> <p>13 formation of scar tissue after the</p> <p>14 surgery?</p> <p>15 A. No, absolutely not. It has</p> <p>16 nothing to do with that. Unless she's</p> <p>17 talking about vaginal dilators to help</p> <p>18 prevent scarring of the vagina. But</p> <p>19 physical therapy alone does not help with</p> <p>20 that.</p> <p>21 Q. So you think she's just</p> <p>22 wrong on this?</p> <p>23 A. I didn't say that. The note</p> <p>24 is not clear.</p> | <p style="text-align: right;">Page 116</p> <p>1 have no benefit.</p> <p>2 Q. She refers to the -- her</p> <p>3 impression -- well, strike that.</p> <p>4 You can have vaginal</p> <p>5 scarring after any type of vaginal</p> <p>6 procedure; would you agree with that?</p> <p>7 A. In varying degrees,</p> <p>8 severity, progression, permanence,</p> <p>9 inability to fix, that can happen with</p> <p>10 procedures.</p> <p>11 But, again, there's going to</p> <p>12 be variables with each procedure.</p> <p>13 Q. Right. But it's something</p> <p>14 that's well known and expected, correct?</p> <p>15 A. Well, no. It depends upon</p> <p>16 who you're talking to, their level of</p> <p>17 knowledge, their level of experience.</p> <p>18 And then, again, in varying degrees.</p> <p>19 Not all doctors read the</p> <p>20 same books, attend the same meetings.</p> <p>21 There's variable --</p> <p>22 Q. You agree that Dr. Kim</p> <p>23 testified that she was aware of the risk</p> <p>24 of scarring and scarification?</p> |
| <p style="text-align: right;">Page 115</p> <p>1 Who knows what she's</p> <p>2 thinking. If she's talking about vaginal</p> <p>3 dilators, sometimes they'll use various</p> <p>4 different vaginal procedures and</p> <p>5 stretching. If they're talking about</p> <p>6 that physical therapy, yes. But that</p> <p>7 falls into the pelvic floor rehab.</p> <p>8 So I can't state what she's</p> <p>9 talking about here. And if she's</p> <p>10 referring to the vaginal dilators, then,</p> <p>11 yes, that will help reduce the narrowing</p> <p>12 and aggressive scarring of the vagina.</p> <p>13 Q. And Ms. Smith hasn't done</p> <p>14 any type of PT after the surgery, right?</p> <p>15 A. I'm not aware of her doing</p> <p>16 any, no.</p> <p>17 Q. Then she also states,</p> <p>18 Discussed need for perioperative vaginal</p> <p>19 estrogen to improve healing.</p> <p>20 Do you have any disagreement</p> <p>21 with that part of the plan?</p> <p>22 A. For mesh exposure, I think</p> <p>23 it probably plays a role. For mesh</p> <p>24 scarring, mesh arm contraction, it will</p> | <p style="text-align: right;">Page 117</p> <p>1 A. She was aware of what she</p> <p>2 knew but not the full extent of it, as</p> <p>3 we've talked about before.</p> <p>4 Q. Well, again, you don't know</p> <p>5 the full extent of what she knows?</p> <p>6 A. I don't. I'm playing odds</p> <p>7 that she has not reviewed what I've</p> <p>8 reviewed. And she knows what she knows,</p> <p>9 and I have no argument against that.</p> <p>10 Q. But there's expected to be a</p> <p>11 certain amount of scarring around any</p> <p>12 type of pelvic mesh that's implanted;</p> <p>13 would you agree with that?</p> <p>14 A. All meshes have been shown</p> <p>15 to increase fibrosis and scarring. Not</p> <p>16 all meshes are the same, so there would</p> <p>17 be varying degrees of mesh scarring with</p> <p>18 a specific product.</p> <p>19 Q. And how do you define banded</p> <p>20 as you refer to it in your report? Is</p> <p>21 that related to scarring?</p> <p>22 A. That is a function of</p> <p>23 scarring and the product design. And</p> <p>24 that's referring to, usually, the mesh</p> |

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| <p style="text-align: right;">Page 118</p> <p>1 arms, as when they're pulled through, 2 they roll and contract and cause banding. 3 They are palpable, you can feel it. 4 There's a very classic feel to it. 5 Q. Here, Dr. Denman advised 6 against removing the arms, she doesn't 7 feel there's any problems related to the 8 arms. 9 Would you agree with that? 10 A. No, I disagree -- I mean, I 11 agree not to remove the arms, that is a 12 risky, dangerous surgery without any 13 clear benefit. 14 Now, some surgeons around 15 the United States still do that, or are 16 trying to do it. We still don't know if 17 that's the right way to go. I personally 18 do not remove the arms. Again, it's a 19 very, very difficult, morbid procedure 20 with the risk/benefit ratio more on the 21 risk. 22 So it's not that Dr. Denman 23 didn't think that was the source of the 24 problem, she didn't feel that it would</p> | <p style="text-align: right;">Page 120</p> <p>1 A. I'm just going off of what 2 her note is here. And it seems pretty 3 clear here. Again, thick banding 4 anterior wall painful to palpation, 5 approximately 2 centimeters in width at 6 max with lateral arms, question mark, 7 obturator. 8 And so I don't know -- we'd 9 have to look at her exact testimony, 10 which may be helpful. But this, to me, 11 seems pretty clear. 12 But, again, if I were her in 13 her situation, I would not go after 14 removing those mesh arms. 15 Q. Let's look at her deposition 16 testimony. If you can hand him Dr. 17 Denman's transcript from June 13th, 2019. 18 MS. GRIFFIN: I'm sorry, 19 Eric, that came in spotty. But we 20 will mark Dr. Denman's deposition 21 testimony from June 13th, 2019. 22 And that will be Exhibit-12. 23 - - - 24 (Whereupon, Exhibit</p> |
| <p style="text-align: right;">Page 119</p> <p>1 cure the problem. 2 Q. Well, did you read her 3 deposition testimony where she 4 specifically testified that there was no 5 pain at the arms of the mesh? 6 A. Correct. 7 Q. And do you have any reason 8 to disagree with that assessment? 9 A. Based upon the physical exam 10 at that point in time, she touched the 11 right area, I have no reason to doubt it. 12 Q. So there's no evidence that 13 she has pain related to the arms of the 14 mesh, right? 15 A. Well, she had -- she was 16 tender to palpation and she had the thick 17 banding on the anterior wall painful to 18 palpation, 2 centimeters in width at max 19 with lateral arms obturator. So that, to 20 me, tells it's -- the arms are a 21 component to this. 22 Q. But she specifically 23 testified there was no pain at the arms 24 of the mesh?</p> | <p style="text-align: right;">Page 121</p> <p>1 Elliott-12, 6/13/19 Deposition 2 Testimony of Dr. Mary Denman, was 3 marked for identification.) 4 - - - 5 THE WITNESS: Okay, I have 6 it. 7 BY MR. BUHR: 8 Q. If you'd go to Page 79. 9 A. You cut out. 10 Q. If you'd go to Page 79. 11 A. Oh, 79. 12 Q. And this is the individual 13 page number. Because on Page -- because 14 there's four pages per page. 15 A. Sure. I'm there. 16 Q. So Page 79, Line 5: So 17 going back to the plan on Page 11, it 18 states here that you didn't find any 19 issues with the arms of the mesh; is that 20 right? 21 Denman responds: Correct. 22 And then further down, Line 23 14: And when you say there were no 24 issues, that's because on examination it</p> |

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| <p style="text-align: right;">Page 122</p> <p>1 was not tender there, right?</p> <p>2 Her answer is: Correct.</p> <p>3 She was not reporting pain</p> <p>4 there, right?</p> <p>5 She responds: Correct.</p> <p>6 So would you agree, then,</p> <p>7 that she wasn't having any pain at the</p> <p>8 site of the arms?</p> <p>9 A. That's what she states. I'm</p> <p>10 just going off -- we have a discrepancy</p> <p>11 between her that-day exam and then what</p> <p>12 she testifies, you know, a year or so</p> <p>13 later.</p> <p>14 But that's what she states.</p> <p>15 There's a discrepancy here.</p> <p>16 Q. Right. Her sworn testimony</p> <p>17 as she's reviewing her records.</p> <p>18 A. Correct, that's what she</p> <p>19 states.</p> <p>20 Q. Are you going to disagree</p> <p>21 with her assessment?</p> <p>22 A. No, that's what she states</p> <p>23 under oath. I have no reason to</p> <p>24 disagree. I was just going off of the</p> | <p style="text-align: right;">Page 124</p> <p>1 Q. Excuse me for a second.</p> <p>2 Are there any more</p> <p>3 conservative options Dr. Denman should</p> <p>4 consider before removing the mesh?</p> <p>5 A. No. Dr. Denman did a nice</p> <p>6 job.</p> <p>7 Your two options, which we</p> <p>8 still do not know, I don't know, even</p> <p>9 though I see this every day, is, what do</p> <p>10 you do with these individuals? Do you</p> <p>11 operate or let them be? And then if you</p> <p>12 do operate, how aggressive do you get?</p> <p>13 It still remains to be defined.</p> <p>14 So I think she did a nice</p> <p>15 job. She felt this -- she felt the mesh,</p> <p>16 so she felt surgery to get rid of the</p> <p>17 mesh was a viable option. So I have no</p> <p>18 criticism. I think she did a nice job.</p> <p>19 Q. Ms. Smith wasn't on any pain</p> <p>20 medications at this point, was she?</p> <p>21 A. No, she was not.</p> <p>22 Q. And she had not done any</p> <p>23 physical therapy, correct?</p> <p>24 A. I am not aware of her doing</p> |
| <p style="text-align: right;">Page 123</p> <p>1 physical exam at the time. But, you</p> <p>2 know, that's what she states later.</p> <p>3 Q. Dr. Denman, in her report,</p> <p>4 there's a reference to that she discussed</p> <p>5 likely nerve damage from FAVD, which I</p> <p>6 believe is forceps-assisted vaginal</p> <p>7 delivery; is that right?</p> <p>8 A. Yes. I would assume so.</p> <p>9 That's not an abbreviation -- I don't do</p> <p>10 any OB, so I assume that.</p> <p>11 Q. Then it goes on, Episiotomy</p> <p>12 with delivery. Reassurance there's not a</p> <p>13 mesh factor involved with this issue,</p> <p>14 speaking of the fecal incontinence.</p> <p>15 And you don't have any</p> <p>16 disagreement with that, do you?</p> <p>17 A. No. A vaginal delivery and</p> <p>18 episiotomy and, I believe, she had four</p> <p>19 or five, maybe even six children, which</p> <p>20 were all decent-sized babies, that,</p> <p>21 logically, is going to cause fecal</p> <p>22 incontinence. And it is -- in my</p> <p>23 opinion, the Avaulta and Align are not</p> <p>24 associated with fecal incontinence.</p> | <p style="text-align: right;">Page 125</p> <p>1 any physical therapy.</p> <p>2 Q. And she was periodically on</p> <p>3 estrogen but not consistently, correct?</p> <p>4 A. Correct. As I stated</p> <p>5 before, it won't help with mesh-related</p> <p>6 pain. But you are correct, she took it</p> <p>7 intermittently.</p> <p>8 Q. Can trigger point injections</p> <p>9 help pelvic pain like this?</p> <p>10 A. Due to the mesh, no. Due to</p> <p>11 pelvic floor myalgia muscle spasms, they</p> <p>12 may play a role and have shown some</p> <p>13 success.</p> <p>14 Q. Then they proceeded to the</p> <p>15 explant on November 15th, 2018.</p> <p>16 A. Okay.</p> <p>17 Q. And she was noted to have</p> <p>18 moderate scarring; is that right?</p> <p>19 A. That is what she states,</p> <p>20 Moderate scarring of contracted mesh at</p> <p>21 the level of the trigone/UBJ.</p> <p>22 Q. And, again, you're going to</p> <p>23 have scarring with any type of vaginal</p> <p>24 mesh procedure, right?</p> |

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| <p style="text-align: right;">Page 126</p> <p>1 A. In varying degrees, 2 dependent upon the specific mesh, you 3 will have some. 4 Q. It notes that she removed, 5 quote, blue mesh; is that right? 6 Do you see that? 7 A. Yes. She makes a 8 specific -- midline blue mesh was noted, 9 meaning that in the middle of that, there 10 was some that was blue. 11 Q. And you would agree with me 12 that that would be the Avaulta mesh? 13 A. That is correct. 14 Q. And Dr. Denman noted that 15 the tissue was really thin, the vaginal 16 tissue. 17 Is that possibly due to not 18 using estrogen cream consistently? 19 A. It's due to the presence of 20 the mesh causing chronic inflammation and 21 pending erosion -- excuse me, exposure. 22 And there's granulation tissue, meaning 23 poor healing. 24 Q. Every patient heals</p> | <p style="text-align: right;">Page 128</p> <p>1 If vaginal atrophy, just 2 using logic here, were a major aspect of 3 poor vaginal healing, then all of the 4 hundreds of transvaginal repairs I do 5 without a foreign body would also be 6 breaking down and having exposure, and 7 they're not. I don't get any, zero. 8 We watch our patients very 9 closely with questionnaires, telephone 10 follow-ups, seeing them back in clinic, 11 wound breakdowns in the vagina. 12 With meshes, you know, there 13 is the known risk of the granulation 14 tissue -- granulation tissue, poor 15 healing, inflammatory process. 16 So I'm saying in Ms. Smith, 17 looking at all the factors, the presence 18 of the foreign bodies and the 19 inflammation is causing her thin tissue 20 breaking down and the scarring is causing 21 the pain. 22 Q. But would you agree with me 23 that not every patient that has 24 transvaginal mesh results in vaginal</p> |
| <p style="text-align: right;">Page 127</p> <p>1 differently, would you agree with that? 2 A. Well, no. I mean, there can 3 be certain patient factors that can slow 4 it down or speed it up. There can be 5 variations there. 6 Q. And what patient factors -- 7 what patient factors are those? 8 A. Chronic steroid use, 9 perhaps; markedly advanced age, perhaps. 10 But we're talking with -- 11 the vagina is different than with 12 abdominal procedures. So the vaginal 13 estrogen content would probably be one. 14 But the presence, also, of a 15 foreign body in there is the main factor. 16 Q. And vaginal atrophy can be a 17 factor. 18 But if I understand your 19 testimony right, you believe that vaginal 20 atrophy itself was caused by the mesh in 21 some fashion? 22 A. Well, I'm saying that's a 23 contributing factor, a major contributing 24 factor.</p> | <p style="text-align: right;">Page 129</p> <p>1 atrophy and thinning of the vaginal wall? 2 A. You are correct. Not every 3 patient has bad outcomes like Ms. Smith. 4 Q. Right. So in some fashion, 5 it's a patient factor? 6 A. Well, no, I disagree with 7 that. I mean, if there's a known risk 8 factor that we can point at in Ms. Smith 9 that the Bard people know about, then 10 it's got to be in the IFU. But there's 11 nothing in there. 12 They have some 13 contraindications, I believe, it's just 14 for pregnancy, bleeding problems. But 15 that's it. So to blame her is to be 16 blaming, what, 20, 30 percent of the 17 patients who have Avaulta? So I don't 18 think that's right. I don't have any 19 logic to go off of for that. 20 Q. The fact is that some 21 patients have complications from 22 surgeries and some patients don't? 23 A. That is a fact, yes. 24 Q. Right?</p> |

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| <p style="text-align: right;">Page 130</p> <p>1 A. Correct.</p> <p>2 Q. So, then, after the</p> <p>3 procedure -- well, first, let me confirm,</p> <p>4 the Align sling is still performing as</p> <p>5 intended in correcting the stress urinary</p> <p>6 incontinence, correct?</p> <p>7 A. From everything I know at</p> <p>8 this point, you are correct.</p> <p>9 Q. And I believe her last --</p> <p>10 well, let's look at your report.</p> <p>11 You reference a visit with</p> <p>12 Dr. Denman on December 3rd, 2018 on Page</p> <p>13 17 of your report.</p> <p>14 A. Correct.</p> <p>15 Q. And I think that might be an</p> <p>16 incorrect date.</p> <p>17 MR. BUHR: Let's attach as</p> <p>18 Exhibit-12 the report from Dr.</p> <p>19 Denman, January 2nd, 2019.</p> <p>20 MS. GRIFFIN: Okay. We will</p> <p>21 be attaching this as Exhibit-13.</p> <p>22 - - -</p> <p>23 (Whereupon, Exhibit</p> <p>24 Elliott-13, 1/2/19 Dr. Mary Denman</p> | <p style="text-align: right;">Page 132</p> <p>1 Q. Okay. So for the December</p> <p>2 3rd, you have a, quote, Small area of</p> <p>3 midline granulation tissue.</p> <p>4 Well, actually, I think the</p> <p>5 quote is that there was a separation</p> <p>6 along the incision with good granulation</p> <p>7 tissue.</p> <p>8 Do you see that on Page 33?</p> <p>9 A. Yes, I do. I -- yeah, so</p> <p>10 the December 3rd quote -- well, there's</p> <p>11 not a quote. It says, Small separation</p> <p>12 of vaginal incision measuring less than</p> <p>13 .5 centimeters.</p> <p>14 And then I do quote the</p> <p>15 follow-up visit on January 2nd, that's</p> <p>16 what you were referring to. But I don't</p> <p>17 see the physical exam on that one.</p> <p>18 Q. Okay. We'll just -- that</p> <p>19 makes sense. Sticking with Page 33.</p> <p>20 Do you know what she means</p> <p>21 by "good granulation tissue"? What does</p> <p>22 that mean to you as a doctor?</p> <p>23 A. This is a fresh post-op.</p> <p>24 This is two weeks after surgery. You</p> |
| <p style="text-align: right;">Page 131</p> <p>1 Report, was marked for</p> <p>2 identification.)</p> <p>3 - - -</p> <p>4 THE WITNESS: Okay, I have</p> <p>5 it.</p> <p>6 BY MR. BUHR:</p> <p>7 Q. So not that it's a</p> <p>8 controversial issue, but just for the</p> <p>9 accuracy of the report, what you</p> <p>10 reference here as December 3rd, 2018</p> <p>11 appears to be from this January 1st -- I</p> <p>12 might be corrected.</p> <p>13 A. I think it's correct. If we</p> <p>14 look at Bates Number 32, that's 12 --</p> <p>15 it's, what, two pages in? 12/3/18, first</p> <p>16 post-op exhibit. Then if you go to Page</p> <p>17 33, exam, vaginal incision. And then</p> <p>18 that's less than 5 centimeters</p> <p>19 separation. So I think that date is</p> <p>20 correct.</p> <p>21 Q. You're right.</p> <p>22 In your report, you don't</p> <p>23 have the January 2nd, 2019 report, right?</p> <p>24 A. That is correct, yes.</p> | <p style="text-align: right;">Page 133</p> <p>1 expect to see granulation tissue there.</p> <p>2 It just means that it's in</p> <p>3 the very early healing periods. It's</p> <p>4 healing appropriately.</p> <p>5 Q. And it was nontender to</p> <p>6 palpation on December 3rd, 2018?</p> <p>7 A. That is correct.</p> <p>8 Q. And then going to January</p> <p>9 2nd, 2019, which is the last report we</p> <p>10 have -- is that right? This is the last</p> <p>11 report we have from the doctor?</p> <p>12 A. That's the last that I have,</p> <p>13 yes.</p> <p>14 Q. And her vaginal exam is</p> <p>15 nontender?</p> <p>16 A. Correct.</p> <p>17 Q. And there's a small area of</p> <p>18 midline granulation tissue?</p> <p>19 A. Correct. That's in my</p> <p>20 report and on this -- from this date.</p> <p>21 Q. And she prescribes estrogen</p> <p>22 again for her?</p> <p>23 A. I don't know if she</p> <p>24 prescribed it. But it states, Estrace to</p> |

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| <p style="text-align: right;">Page 134</p> <p>1 vagina, which would be an estrogen cream.</p> <p>2 Q. And that would be to help</p> <p>3 with the healing?</p> <p>4 A. Correct.</p> <p>5 Q. And she okays her for</p> <p>6 intercourse after two weeks.</p> <p>7 Do you have any criticism of</p> <p>8 that, based on what the exam showed?</p> <p>9 A. I personally would wait</p> <p>10 until it's completely, 100 percent,</p> <p>11 healed up. So I don't go by a date. Six</p> <p>12 weeks out is usual timeframe. And so</p> <p>13 she's postponing it another two weeks.</p> <p>14 So Dr. Denman's assessment</p> <p>15 was that it would be safe at that point</p> <p>16 in time.</p> <p>17 Q. But she doesn't examine her</p> <p>18 and confirm that the healing is complete</p> <p>19 before authorizing intercourse; is that</p> <p>20 fair?</p> <p>21 A. I do not see that in the</p> <p>22 records anywhere.</p> <p>23 Q. And if Ms. Smith had vaginal</p> <p>24 intercourse before the -- her vaginal</p> | <p style="text-align: right;">Page 136</p> <p>1 completely healed, can that contribute to</p> <p>2 continued healing problems?</p> <p>3 MS. SCARCELLO: Same</p> <p>4 objection.</p> <p>5 THE WITNESS: I would agree</p> <p>6 with you. It's definitely not</p> <p>7 going to help.</p> <p>8 BY MR. BUHR:</p> <p>9 Q. <u>And you, in your report, are</u></p> <p>10 <u>offering certain opinions about Ms.</u></p> <p>11 <u>Smith's likely prognosis; is that right?</u></p> <p>12 A. <u>That is correct.</u></p> <p>13 Q. <u>And you describe her</u></p> <p>14 <u>prognosis as poor?</u></p> <p>15 A. <u>That is correct.</u></p> <p>16 Q. <u>And you wrote this report</u></p> <p>17 <u>before reading Dr. Denman's testimony; is</u></p> <p>18 <u>that right?</u></p> <p>19 A. <u>That is -- yes, that is</u></p> <p>20 <u>correct.</u></p> <p>21 Q. <u>And Dr. Denman testified</u></p> <p>22 <u>that her pain and dyspareunia is markedly</u></p> <p>23 <u>improved since the 2018 surgery; is that</u></p> <p>24 <u>right?</u></p> |
| <p style="text-align: right;">Page 135</p> <p>1 wall had completely healed, could that</p> <p>2 contribute to continued problems healing?</p> <p>3 MS. SCARCELLO: Objection.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: Well, I would</p> <p>6 need to know -- I mean, we're</p> <p>7 talking in theory here.</p> <p>8 With this small area of</p> <p>9 midline granulation tissue, I</p> <p>10 don't know how extensive that is.</p> <p>11 I feel that Dr. Denman, in her</p> <p>12 experience, must have felt it was</p> <p>13 mild. And then two weeks would</p> <p>14 have been safe.</p> <p>15 If she went -- preceded</p> <p>16 those two weeks, or within that</p> <p>17 two weeks had intercourse, that</p> <p>18 might not be the ideal. If she</p> <p>19 waited until afterwards, Dr.</p> <p>20 Denman felt it was safe.</p> <p>21 BY MR. BUHR:</p> <p>22 Q. Thank you. But I think my</p> <p>23 question was, if you have sexual</p> <p>24 intercourse before the vaginal wall is</p> | <p style="text-align: right;">Page 137</p> <p>1 A. <u>That is correct.</u></p> <p>2 And that is also my</p> <p>3 experience on early post-ops after</p> <p>4 meshes. You usually have a period that</p> <p>5 the pain is less and it comes back, in my</p> <p>6 experience, and in the experience of</p> <p>7 individuals who have written papers on</p> <p>8 this subject.</p> <p>9 I hope it doesn't, but it</p> <p>10 usually comes back.</p> <p>11 Q. So are you saying -- are you</p> <p>12 offering an opinion, to a reasonable</p> <p>13 degree of medical certainty, that her</p> <p>14 pain is going to return?</p> <p>15 A. Based upon my experience, my</p> <p>16 attendance at national/international</p> <p>17 meetings and my giving lectures on the</p> <p>18 subject, my dealing with patients, and</p> <p>19 I've operated on these types of patients,</p> <p>20 that the odds are greatly that pain will</p> <p>21 come back.</p> <p>22 Q. So can you state, with a</p> <p>23 reasonable degree of medical certainty,</p> <p>24 that the pain will come back?</p> |

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| <p style="text-align: right;">Page 138</p> <p>1 A. Just as I already stated, 2 with all those aforementioned criteria, 3 that pain usually does come back. 4 And that's why I have chosen 5 to stop operating for these conditions 6 for pain. And that's also based upon a 7 paper by Ho, et al., H-O, et al., where 8 the poor success of operating for pain, 9 because it doesn't work. 10 Q. But you would at least agree 11 that at this point it's markedly 12 improved? 13 A. Correct. And that is 14 wonderful. And I hope I'm wrong. And if 15 I'm wrong, that's wonderful for Ms. 16 Smith. 17 I just -- in my experience, 18 it doesn't last. 19 Q. So it may come back but it 20 may not; is that fair? 21 A. The odds are, based, again, 22 the Ho, et al. -- I believe it's Ho, it's 23 a Zimmerman -- Phillipe, Zimmerman, at UT 24 Southwestern, talks about roughly a 70</p> | <p style="text-align: right;">Page 140</p> <p>1 Q. Did you see Denman's 2 testimony that she could not conclude the 3 cause of it? 4 A. Yeah, we would have to look 5 at the specific report. I recall her 6 stating that. 7 Q. And she didn't note any 8 muscle pain prior to the explant in the 9 same area; is that right? 10 A. Again, we need to look at 11 the specifics. I would be going off of 12 memory, so it wouldn't be fair. I have 13 the report here. 14 Q. Well, we don't have the 15 report from -- 16 A. I'm sorry, deposition. I'm 17 sorry, you said deposition, I thought. 18 Q. I think it's on Page 55. 19 A. Okay. I'm there. 20 Q. So she was having a little 21 increased pain? 22 A. Correct. That's what I'm -- 23 that's what I'm describing. In my 24 experience, that fits perfectly.</p> |
| <p style="text-align: right;">Page 139</p> <p>1 percent chance that the pain comes back 2 or is not cured by surgery. 3 Again, if I'm wrong, that 4 would be wonderful for her. But, 5 unfortunately, experience has told me 6 otherwise. I've had many patients. I do 7 surgery on it, and they have great pain 8 relief, and we're thrilled, and then 9 disappointed months later or years later. 10 Q. In Dr. Denman's testimony, 11 she describes some more -- a more recent 12 visit with Dr. -- I'm sorry, let me start 13 over. 14 In Dr. Denman's testimony, 15 she discusses a more recent visit with 16 Ms. Smith where she had some lateral 17 muscle pain. 18 Are you offering any opinion 19 about the cause of that lateral muscle 20 pain? 21 A. I would have to see that 22 actual report before I could state 23 definitively. Lateral is very worrisome 24 for the arm pain, mesh contraction.</p> | <p style="text-align: right;">Page 141</p> <p>1 You have an initial good 2 response, and then it comes back. Again, 3 I wish I were wrong, but that's what 4 happens. 5 Q. But do you see how she 6 describes this as muscle pain on Line 9? 7 A. Correct. 8 Q. And then says she does 9 not -- she does not know what's causing 10 that muscle pain? 11 A. Yeah. I agree she doesn't 12 know what's causing it. 13 Q. So I'm saying, to a 14 reasonable degree of medical certainty, 15 she doesn't know what's causing it, can 16 you state -- you can't state, to a 17 reasonable degree of medical certainty, 18 what's causing it without examining the 19 patient, correct? 20 A. An exam would be very 21 beneficial. I can state, based upon my 22 experience of doing probably hundreds of 23 these, that she has pain that's coming 24 back. It's in the muscles due to the</p> |

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1 presence of the arms; going through the
 2 various different muscles from the
 3 obturator foramen bilaterally.
 4 Dr. Denman, no criticism to
 5 her at all, doesn't know because she just
 6 hasn't done these. This is probably her
 7 one and only time she's done this. So I
 8 don't criticize her. She doesn't know,
 9 she admits it, which is very admirable.
 10 And I'm saying, with a
 11 reasonable degree of medical certainty,
 12 it's due to the presence of the mesh
 13 arms.
 14 Q. If you'd turn to Page 35 of
 15 her deposition.
 16 A. Okay, I'm there.
 17 Q. The very last -- Lines 24
 18 and 25, where it says she didn't have any
 19 muscle pain, so this was prior to the
 20 explant, she didn't have pain in the same
 21 area where she's complaining of pain now.
 22 So wouldn't that make it
 23 less likely to be related to the mesh?
 24 A. It's a progression of the

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1 fibrosis and scarring. They know from
 2 animal models, from, like, Closter,
 3 Hoffin and others, that the mesh
 4 extraction continues indefinitely. They
 5 have dog studies 15 years, 20 years out.
 6 So this is the natural progression of it.
 7 Q. After the mesh -- the
 8 central part of the mesh connecting the
 9 arms has been removed?
 10 A. Yes. But the mesh arms are
 11 still going through the obturator foramen
 12 connected to -- off the top of my head I
 13 would say it's six or seven different
 14 muscles. So the mesh continues to
 15 contract, and you get continued pain.
 16 Q. Does Ms. Smith have back
 17 pain, lower back pain?
 18 A. Yes, she does.
 19 Q. Can that radiate into the
 20 pelvis area?
 21 A. Not causing specific
 22 pinpoint pain. That's where an exam
 23 would help sort that out.
 24 But back pain is in the

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1 back. You can have radiculopathies going
 2 down the legs. Again, it just depends
 3 upon where this pelvic pain is.
 4 If it's mid vault, is it
 5 obturator foramen versus if it's in the
 6 low back -- if it's in the low back, I
 7 agree with you, it's not due to the mesh.
 8 Q. And we just don't have the
 9 detailed descriptions, as we sit here
 10 today, to completely rule out pain
 11 radiating from her back?
 12 A. Well, I have no medical
 13 records describing her back pain and
 14 where that pain is and where it radiates
 15 to. If we had that, that would help sort
 16 out the issue.
 17 I'm saying that when you put
 18 all the factors together of having a
 19 large volume of mesh put through the
 20 obturator foramen, having mesh
 21 contraction and pain, removing it, and in
 22 my experience, in the literature, 50 to
 23 70 -- 30 to 50 percent mesh arm
 24 contraction rate, everything fits as far

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1 as it being with mesh.
 2 But definitively answering
 3 the question would require either an IME
 4 or an advanced expert to examine her and
 5 telling us otherwise.
 6 Q. But you would agree that the
 7 pain is still markedly improved over
 8 prior to the explant?
 9 A. I can't say that. She says
 10 it's increased. But it's -- there's no
 11 indication that it's back to where it
 12 was. I forget, we were on Page 35, I
 13 believe.
 14 Q. 55.
 15 A. 55.
 16 Q. She describes it as having a
 17 little increase in pain.
 18 A. Yeah. So that would imply,
 19 to answer your question, yes. As of
 20 that -- the last exam, which I don't have
 21 the records from that, she states she was
 22 having a little increase in pain. You're
 23 correct.
 24 Q. Do you have any opinion on

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1 what future care Ms. Smith may need?

2 A. In my opinion, the only
 3 chance for some improvement would be very
 4 aggressive advanced-level physical
 5 therapy, biofeedback, bladder retraining;
 6 questionable injections into the mesh,
 7 around the mesh. In my experience, that
 8 has worked very poorly.

9 The other option is surgery
 10 to remove the mesh arms. In my
 11 experience, that tends not to work very
 12 well and can make the pain worse. There
 13 are surgeons around the nation who do go
 14 after that. I have just felt the risk
 15 outweighs the benefit.

16 So she has options, none of
 17 them are really good options.

18 Q. That would depend on whether
 19 her pain returns and, if so, how much --

20 A. Correct.

21 Q. -- right?

22 A. Correct.

23 Q. So as of today, you're not
 24 offering an opinion that she's going to

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1 require any further surgeries; is that
 2 fair?

3 A. I'm saying that I would have
 4 to wait and watch with time. If she only
 5 now, or whenever this last exam was, has
 6 a little increase in pain, then she
 7 should not undergo surgery.

8 Q. Do you have any opinion as
 9 to whether she will require future
 10 surgery to repair her rectocele?

11 A. Well, a rough estimate is
 12 that roughly a third of women have their
 13 prolapse progress to needing surgery. So
 14 that's just a rough idea.

15 But it would be immaterial
 16 to the Avaulta. It's a separate problem.

17 Q. Right. But further
 18 surgeries related to -- for an unrelated
 19 rectocele could result in more pelvic
 20 pain and dyspareunia, correct?

21 A. Well, we're talking, in
 22 theory, she could. But she wouldn't have
 23 any mesh-related pain. Again, we're
 24 talking in theory.

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1 Right now she doesn't
 2 warrant it. So I don't have specifics
 3 where I can give an answer to that one.

4 Q. But, in general, in terms of
 5 the known risks of repair of pelvic organ
 6 prolapse, it can result in pelvic pain
 7 and dyspareunia, right? Even without
 8 mesh?

9 A. You have to put qualifiers
 10 on there. There's varying degrees,
 11 severity, progression, inability to fix
 12 it. But the posterior prolapse can be
 13 associated with it. But, again, it's not
 14 to the severity that we see with the
 15 meshes.

16 Q. And if she would have had --
 17 one of -- well, let me start over.

18 One of the safer
 19 alternatives that you allege in your
 20 report is repair with biologics. And
 21 that's both for stress urinary
 22 incontinence and pelvic organ prolapse.

23 But those types of repairs
 24 also include the risk of pelvic pain and

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1 dyspareunia, right?

2 A. Not to the degree that we
 3 see with the meshes and the severity and
 4 the progressive nature of it. So no.

5 Q. But there's risks and
 6 benefits to both of those procedures,
 7 right? And the doctor has to make that
 8 risk/benefit analysis?

9 A. If that physician, he or she
 10 knows all of the risks known to the
 11 company, the severity, the progressive
 12 nature of it, and the inability to repair
 13 it with the meshes -- again, there's too
 14 many variables to give a blanket
 15 statement to.

16 Q. Let me say it this way:
 17 Using a biologic -- which, first of all,
 18 a biologic is not a similar product; it's
 19 a completely different product, right?

20 A. It is a non-mesh product,
 21 yes.

22 With her situation,
 23 biologics would be way down the list. It
 24 would just be use of standard absorbable

| | |
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| <p style="text-align: right;">Page 150</p> <p>1 sutures that cost \$5, would be what I 2 would do with her.</p> <p>3 Q. For the treatment of her 4 pelvic organ prolapse?</p> <p>5 A. Correct. With the stage 2 6 anterior prolapse like she had, a 7 standard suture repair of five or six 8 sutures, or less, that cost all of, 9 again, \$5, would be what I'd do.</p> <p>10 I would not go down the 11 route of biologics. They are 12 theoretically an option. But she had a 13 relatively mild prolapse, so I wouldn't 14 do that. It's an option, but it wouldn't 15 be what I would do.</p> <p>16 Q. So, again, that's not 17 utilizing any type of transvaginal mesh, 18 then?</p> <p>19 A. Correct.</p> <p>20 Q. What about for treatment of 21 stress urinary incontinence?</p> <p>22 A. Then you can use her own 23 tissue. You can use tissue from a tissue 24 bank. Then you could use biologics.</p> | <p style="text-align: right;">Page 152</p> <p>1 things.</p> <p>2 Q. The main reason the 3 community, medical community, was looking 4 towards polypropylene mesh was to 5 increase -- or, rather, decrease the risk 6 of recurrence, correct?</p> <p>7 A. That was the goal, which is 8 an admirable goal. However, it didn't 9 pan out that way. And so the anatomic 10 repair rate was possibly better in the 11 anterior vaginal vault. But apical and 12 posterior, there was no benefit. So the 13 reoperation rate was the same.</p> <p>14 So you increase the 15 complications for the woman without 16 giving her a significant benefit.</p> <p>17 Q. Plaintiff's implant 18 procedure was in January 2008, right?</p> <p>19 A. Correct.</p> <p>20 Q. The only safer alternative 21 that you list that's specific to vaginal 22 mesh is a lighter-weight, larger-pore 23 polypropylene mesh, right?</p> <p>24 A. Correct.</p> |
| <p style="text-align: right;">Page 151</p> <p>1 Others are available. Using her own 2 tissue is the easiest and cheapest.</p> <p>3 Q. And the use of biologics 4 wouldn't completely eliminate her risk of 5 pelvic pain and dyspareunia, correct?</p> <p>6 A. As we mentioned before, I go 7 based upon my previous testimony, 8 depending on the severity, the frequency, 9 the progressive nature of it and the 10 inability to repair it is going to be 11 different with the biologics.</p> <p>12 You don't see those problems 13 with it. You see recurrence, but you 14 don't see those other chronic, lifelong 15 problems.</p> <p>16 Q. But recurrence is a major 17 consideration in determining what 18 procedure is best for the patient, would 19 you agree?</p> <p>20 A. It is a consideration. If 21 you asked the patient, would you rather 22 have a recurrence of your prolapse or 23 lifelong pain and inability to have 24 intercourse, those are two different</p> | <p style="text-align: right;">Page 153</p> <p>1 Q. And are you aware of a 2 midurethral sling, at that time, that 3 meets the description in your report?</p> <p>4 A. Well, I talked about POP 5 repair. I didn't mention anything as far 6 as a sling.</p> <p>7 So that Point Number 3 on 8 Page 19 is a POP repair using a 9 lighter-weight, large-pore mesh. So 10 that's not pertinent to the sling.</p> <p>11 Q. What about Number 4 on Page 12 20?</p> <p>13 A. Correct. I am not aware of 14 there being an on-the-market, available, 15 a lightweight, large-pore mesh sling. 16 There were trials of them, but they were 17 never released.</p> <p>18 Q. But you believe there was a 19 POP, pelvic organ prolapse, mesh that's 20 lighter weight and larger pore --</p> <p>21 A. Ethicon had --</p> <p>22 Q. -- in 2008?</p> <p>23 A. I'm sorry, I interrupted 24 you.</p> |

| | |
|---|--|
| <p style="text-align: right;">Page 154</p> <p>1 I cannot specifically state 2 to 2008. Ethicon did have a product that 3 was out there, but didn't have the arms. 4 The arms are what causes a significant 5 component of the problem with pain. 6 That's what I'm saying, is 7 that this particular patient, Ms. Smith, 8 did not need those advanced-level 9 repairs. It was a first-time surgery 10 with a low-grade prolapse. 11 Q. And even if there was a 12 lighter-weight, larger-pore mesh 13 available at the time, it wouldn't have 14 eliminated her risk for pelvic pain or 15 dyspareunia or extrusion, correct? 16 A. Let's break that down. 17 That's a -- what I call a compound 18 question. I don't know what you guys 19 call it. 20 We have to define the type 21 of mesh we're doing. If all you're doing 22 is a mesh without the arms -- see, the 23 arms are a major source of the problem -- 24 so your risk of extrusion would</p> | <p style="text-align: right;">Page 156</p> <p>1 Q. But to answer my question, 2 it wouldn't have eliminated her risk of 3 pelvic pain or dyspareunia or extrusion? 4 A. Correct. It would lower it, 5 but not eliminate it. 6 Q. I don't want to retread 7 grounds from your generic deposition, but 8 you're not aware of any more recent 9 literature finding that the Bard mesh, 10 the Avaulta, has a higher risk of any 11 complications as compared to any other 12 transvaginal mesh; is that fair? 13 A. As I'm sitting here right 14 now, I cannot recall off the top of my 15 head a document such as that. But I 16 would have to look through the literature 17 for it. And since it's been pulled off 18 the market, no one is researching it. 19 Q. So it's possible, if she had 20 a different pelvic organ prolapse mesh, 21 that she would have had dyspareunia and 22 pelvic pain and extrusion, correct? 23 MS. SCARCELLO: Object to 24 form.</p> |
| <p style="text-align: right;">Page 155</p> <p>1 theoretically be the same, as long as it 2 doesn't have the, you know, like the 3 Avaulta Plus has that confounding factor 4 of the extra layer of tissue on it. 5 And then you said pelvic 6 pain. Pelvic pain may be less because 7 you don't have the arms. 8 And I think you said a third 9 thing there, I forget what that was. You 10 had three. 11 Q. Dyspareunia. 12 A. Dyspareunia. Dyspareunia 13 has a chance of being less when you don't 14 have the arms, because you don't have the 15 mesh contraction and the pulling that you 16 get with those things. 17 So that would -- I know 18 surgeons who still will put in those 19 grafts without the arms. I personally 20 don't. I don't think there's a need for 21 it. 22 And, again, in Ms. Smith's 23 situation, she didn't need it. She just 24 needs standard sutures.</p> | <p style="text-align: right;">Page 157</p> <p>1 THE WITNESS: Well, it 2 depends what we're talking about. 3 Are we talking about, like, 4 the Prolift? anterior? Are we 5 talking about the Monarc product? 6 Excuse me, not Monarc, American 7 Medical Systems, the Apogee and 8 the Perigee? There's a lot out 9 there. All of them have their 10 known risks to it. 11 Again, with -- Avaulta is a 12 unique one with having that outer 13 coating to it, which throws in 14 another variable in a situation. 15 But the risk with all meshes 16 is there in varying degrees. 17 BY MR. BUHR: 18 Q. <u>Looking back at the opinions</u> 19 <u>in your report, on Page 18, we talked</u> 20 <u>earlier about Dr. Kim's testimony that</u> 21 <u>she was aware of the risks of erosion,</u> 22 <u>extrusion, pelvic pain, dyspareunia.</u> 23 <u>You recall that discussion,</u> 24 <u>right?</u></p> |

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1 A. Yes, I do.
2 Q. In your report here, you
3 specifically refer to foreign body
4 reaction and chronic inflammatory
5 response related to the Bard products.
6 A. Correct.
7 Q. Would you agree that Dr. Kim
8 specifically testified that she was aware
9 of those risks?
10 A. As I've already stated, she
11 was aware of what she knows, but does not
12 know the full extent of it.
13 Q. You also reference painful
14 contracture and banding of the mesh.
15 Would you agree that Dr. Kim
16 testified that she was aware of those
17 risks as well?
18 A. As I stated previously, and
19 I'll rely on the previous testimony, she
20 stated what she knew, and she doesn't
21 know the full extent, as I do and others
22 involved in this, what's going on behind
23 the scenes with the company.
24 Q. So I understand that that's

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1 your testimony, that she didn't know the
2 full extent.
3 But there's no risks that
4 she wasn't aware of that are relevant for
5 Ms. Smith?
6 A. She knew about risks. But
7 she didn't know about the severity, the
8 frequency and the progressive nature of
9 those risks.
10 Q. But she was aware of each of
11 the risks and complications that you're
12 opining Ms. Smith had as a result of the
13 Bard products, right?
14 A. Well, as I've stated, she
15 knew of risks. But she didn't know of
16 the severity, the frequency, the
17 progressive nature and the inability to
18 fix those complications.
19 Q. Her anterior prolapse that
20 was corrected by the Avaulta, that has
21 still not returned, correct?
22 A. Based upon the January 2nd,
23 2019, so, what, six, seven months ago,
24 there was no record of the prolapse

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1 coming back.
2 Q. So both the Align and the
3 Avaulta corrected the conditions for
4 which they were implanted for, right?
5 A. At a certain cost, you are
6 correct.
7 MR. BUHR: That may be all
8 the questions I have. If we can
9 just take a quick break and then
10 come back.
11 THE WITNESS: Sure.
12 VIDEO TECHNICIAN: We're
13 going off record. The time is
14 4:25.
15 - - -
16 (Whereupon, a brief recess
17 was taken.)
18 - - -
19 VIDEO TECHNICIAN: We're
20 going back on record. Media File
21 Number 3. The time is 4:27.
22 BY MR. BUHR:
23 Q. So we talked earlier that
24 Ms. Smith had preexisting depression; is

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1 that right?
2 A. She was on medication for
3 depression. I don't know how severe it
4 was.
5 Q. Can there be a psychological
6 component to dyspareunia?
7 A. Possibly. However, it's not
8 going to cause pinpoint pain and pain at
9 the site of the mesh. That's not --
10 that's not a component of depression.
11 And if depression is a major
12 factor in causing complications with
13 meshes, it needs to be on the IFU, which
14 it's not.
15 So she had a preexisting
16 condition. And that's worrisome if it's
17 not on the IFU, that worsens things.
18 Q. Well, I wasn't suggesting
19 that it was relevant to the mesh.
20 But even without mesh, a
21 patient can have dyspareunia due to
22 psychological issues and depression?
23 A. Well, that's a broad
24 statement. If there's a history of

| Page 162 | Page 164 |
|---|---|
| <p>1 physical trauma, rape, abuse of some 2 sort, that's a different story. That 3 becomes very complicated. 4 But she reported nothing 5 prior to the surgery. This all happened 6 years later. So I don't see a logical 7 connection between the two. 8 Q. Because she didn't have 9 similar complaints prior to the implant? 10 A. Well, the location of the 11 pain, the progressive nature of it, the 12 severity all happen years later. So, 13 again, I don't see a logical connection 14 between the depression and this. 15 Again, if it is a known 16 issue, that's got to be on the IFU. 17 Q. Can depression and general 18 wellbeing affect the healing process in 19 an individual? 20 A. As far as it relates to the 21 vagina, I've never heard of anything 22 related to that. 23 Q. Have we discussed all the 24 opinions you intend to offer in this</p> | <p>1 I'll keep an open mind, based upon 2 what's going on. 3 And the farther she goes out 4 from her revision surgery, it 5 would be important to have a 6 documented exam, too. 7 MR. BUHR: All right, 8 Doctor, I think that's all the 9 questions I have today. 10 MS. SCARCELLO: Nothing from 11 me. 12 VIDEO TECHNICIAN: This 13 concludes today's -- 14 MR. BUHR: Hold on. Before 15 we go off the record. 16 I just want to make sure we 17 have a placeholder exhibit for the 18 invoices that will be provided by 19 counsel's office. 20 - - - 21 (Whereupon, Exhibit 22 Elliott-14, Placeholder, was 23 marked for identification.) 24 - - -</p> |
| Page 163 | Page 165 |
| <p>1 case? 2 A. All my opinions are included 3 in my report. I don't recall if we've 4 discussed every one. 5 We've discussed all the 6 opinions you've asked me. Not to be a 7 smart-mouth about it, but I don't know if 8 there's something else here we haven't 9 discussed. 10 Q. And at this point, you don't 11 have any intention of performing an 12 examination on Ms. Smith? But you 13 might -- you would like to have the 14 opportunity to do that if the case were 15 to go to trial; is that how I understand 16 your testimony? 17 MS. SCARCELLO: Object to 18 form. 19 You can answer. 20 THE WITNESS: Yes. If this 21 case were to go to trial, then I 22 would have to perform an IME 23 prior, to further support or 24 refute my opinions at this point.</p> | <p>1 MR. BUHR: With that, I 2 think we're done. Thank you. 3 MS. SCARCELLO: Thank you. 4 VIDEO TECHNICIAN: This 5 concludes today's deposition. 6 We're going off the record. The 7 time is 4:31. 8 - - - 9 (Whereupon, the deposition 10 concluded at 4:31 p.m.) 11 - - - 12 13 14 15 16 17 18 19 20 21 22 23 24</p> |

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1 CERTIFICATE
2
3
4 I HEREBY CERTIFY that the
5 witness was duly sworn by me and that the
6 deposition is a true record of the
7 testimony given by the witness.
8
9
10
11 Amanda Maslynsky-Miller
12 Certified Realtime Reporter
13 Dated: August 12, 2019
14
15
16
17 (The foregoing certification
18 of this transcript does not apply to any
19 reproduction of the same by any means,
20 unless under the direct control and/or
21 supervision of the certifying reporter.)
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1 INSTRUCTIONS TO WITNESS
2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.
8 After doing so, please sign
9 the errata sheet and date it.
10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.
14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.
21
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1 ACKNOWLEDGMENT OF DEPONENT
2
3 I, _____, do
4 hereby certify that I have read the
5 foregoing pages, 1 - 165, and that the
6 same is a correct transcription of the
7 answers given by me to the questions
8 therein propounded, except for the
9 corrections or changes in form or
10 substance, if any, noted in the attached
11 Errata Sheet.
12
13 DANIEL S. ELLIOTT, MD _____ DATE _____
14
15 Subscribed and sworn
16 to before me this
17 _____ day of _____, 20 _____.
18 My commission expires: _____
19
20 Notary Public
21
22
23
24

Daniel S. Elliott, M.D.

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